PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S2**

1. NAME OF THE MEDICINE

IBUPAIN® FORTE (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each IBUPAIN FORTE capsule contains 200 mg ibuprofen, 10 mg codeine phosphate and 250 mg paracetamol.
IBUPAIN FORTE is sugar free.

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Capsules
Size 0, hard capsule with red body and dark green cap containing a free-flowing white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

IBUPAIN FORTE is indicated for the relief of mild to moderate pain of inflammatory origin with or without fever.

4.2 Posology and method of administration

Posology

DO NOT EXCEED THE RECOMMENDED DOSE.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).

Adults, the elderly, and children over 12 years:

One (1) to two (2) capsules four (4) to six (6) hourly. Do not take more than six (6) capsules in 24 hours. The duration of treatment should be limited to 5 days and if no effective pain relief is achieved, the patients/carers should be advised to seek the views of a medical practitioner.

Elderly:

The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used for the shortest possible duration. The patient should be monitored regularly for gastrointestinal bleeding during NSAID therapy.

Paediatric population:

IBUPAIN FORTE should not be used in children below the age of 12 years because of the risk of opioid toxicity due to the variable and unpredictable metabolism of codeine to morphine (see section 4.3 and section 4.4).

Method of administration

IBUPAIN FORTE capsules are administered orally. The capsules must be swallowed with water and not chewed.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients of IBUPAIN FORTE listed in Section 6.1.
- Respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, convulsive disorders, head injuries and conditions in which intracranial pressure is raised. It should not be given in heart failure secondary to chronic lung disease.
- Concurrent use with Monoamine Oxidase Inhibitors (MAOIs) or within 14 days of stopping such treatment (see section 4.5).
- Diarrhoea associated with pseudomembranous colitis.
- Impaired hepatic and renal function.
- Heart failure.
- Active or history of recurrent peptic ulcer/haemorrhage.
- History of gastrointestinal perforation, ulceration, or bleeding (PUBs), related to previous NSAIDs therapy, including IBUPAIN FORTE.
- Cardiovascular disease.
- Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to acetylsalicylic acid (aspirin) or other nonsteroidal anti-inflammatory medicines (NSAIDs).
- Uncontrolled asthma or bronchospasm.
- Nasal polyps associated with aspirin-induced bronchospasm.
- Patients with bleeding disorders.
- In all paediatric patients (0 – 18 years of age) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions (see section 4.4).
- In patients for whom it is known they are CYP2D6 ultra-rapid metabolisers.
- Pregnancy – risk of foetal renal dysfunction (see section 4.4 and 4.6).
- In women during breastfeeding (see section 4.6).
- Chronic constipation.

4.4 Special warnings and precautions for use

IBUPAIN FORTE contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Dosages in excess of those recommended may cause severe liver damage.
IBUPAIN FORTE is for short term use and is not recommended for use beyond 5 days.
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2 and gastrointestinal and cardiovascular risks below).

Respiratory disorders:

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Acute asthma attack or respiratory impairment or disease – may decrease respiratory drive and increase airway resistance in these patients.

The use of IBUPAIN FORTE with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

Cardiovascular and cerebrovascular effects:

Appropriate monitoring and advice are required for patients with a history of hypertension as fluid retention and oedema have been reported in association with NSAID therapy. In view of IBUPAIN FORTE's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 mg/day) is associated with an increased risk of arterial thrombotic events.

Patients with uncontrolled hypertension, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with IBUPAIN FORTE after careful consideration and high doses (2400 mg/day) should be avoided.

Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Gastrointestinal bleeding, ulceration, and perforation:

Gastrointestinal bleeding, ulceration, or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.

The risk of gastrointestinal Perforation, Ulceration or Bleeding (PUBs) is higher with increasing doses of IBUPAIN FORTE, in patients with a history of ulcers, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly.
These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low-dose aspirin, or other medicines likely to increase gastrointestinal risk (see below and section 4.5).

Patients with a history of gastrointestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors, or anti-platelet agents such as aspirin (see section 4.5).

When gastrointestinal bleeding or ulceration occurs in patients receiving IBUPAIN FORTE, treatment with IBUPAIN FORTE should be stopped.

IBUPAIN FORTE should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as their condition may be exacerbated (see section 4.8).

Cardiovascular, renal, and hepatic impairment:

The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients (see also section 4.3 and 4.8). There is a risk of renal impairment in dehydrated children and adolescents.

Severe hypokalaemia and renal tubular acidosis have been reported due to prolonged use of ibuprofen at higher than recommended doses. This risk is increased with the use of codeine/ibuprofen as patients may become dependent on the codeine component (see warning on opioid use disorder, section 4.8, and section 4.9). Presenting signs and symptoms included reduced level of consciousness and generalised weakness. Ibuprofen induced renal tubular acidosis should be considered in patients with unexplained hypokalaemia and metabolic acidosis.

Severe cutaneous adverse reactions:

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported in association with the use of NSAIDs (see section 4.8). Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Acute Generalised Exanthematous Pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. IBUPAIN FORTE should be discontinued at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as contained in IBUPAIN FORTE. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue IBUPAIN FORTE and evaluate the patient immediately.

Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), eosinophilia, and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have also been reported in patients treated with paracetamol-containing medicines. If a patient develops SCAR, treatment with IBUPAIN FORTE must immediately be discontinued and appropriate treatment instituted.

Masking of symptoms of underlying infections:

IBUPAIN FORTE can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When IBUPAIN FORTE is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

Elderly:

The elderly have an increased frequency of adverse reactions to NSAIDs including IBUPAIN FORTE, especially gastrointestinal Perforation, Ulceration and Bleeding (PUBs) which may be fatal (see section 4.2).

Elderly patients may metabolise or eliminate opioid analgesics more slowly than younger adults. Codeine should be used with caution in the elderly and debilitated patients as they may be more susceptible to the respiratory depressant effects.
Do not take concurrently with any other codeine-containing compounds.

Codeine:

Care is advised in the administration of codeine to patients with hypotension, hypothyroidism, adrenocortical insufficiency, shock, obstructive bowel disorders, acute abdominal conditions (e.g. peptic ulcer), recent gastrointestinal surgery, gallstones, myasthenia gravis, and a history of peptic ulcer or convulsions and also in patients with a history of drug abuse.

The habitual intake of analgesics, especially the combination of different analgesics may cause permanent kidney damage with the risk of renal failure (analgesic nephropathy).

Long-term, inappropriate use of high doses of analgesics may cause headaches, which may not be treated by increasing doses of the medicinal product.

Gallbladder disease or gallstones - may cause biliary tract spasm.

Alcoholism, drug abuse or dependence:

- caution is advised if the patient is predisposed to medicine or drug abuse
- alcohol increases the risk of liver toxicity.

Opioid use disorder (abuse and dependence)

DEPENDENCE MAY DEVELOP WITH PROLONGED USE OF HIGH DOSES.

Tolerance, physical and psychological dependence, and opioid use disorder (OUD) may develop upon repeated administration of opioids such as codeine. Abuse or intentional misuse of IBUPAIN FORTE may result in overdose and/or death.

Serious clinical outcomes, including fatalities, have been reported in association with abuse and dependence with codeine/ibuprofen combinations, particularly when taken for prolonged periods at higher than recommended doses. These have included reports of gastrointestinal perforations, gastrointestinal haemorrhages, severe anaemia, renal failure, renal tubular acidosis, and severe hypokalaemia associated with the ibuprofen component.
Patients should be informed about the risks and signs of OUD as well as serious clinical outcomes. If these signs occur, patients should be advised to contact their doctor.
Withdrawal symptoms, such as restlessness and irritability may occur once the drug is stopped.

Head injury, increased intracranial pressure or intracranial lesions:

Risk of respiratory depression and further increase in intracranial pressure.

IBUPAIN FORTE may also cause sedation and pupillary changes that may obscure the clinical course of head injury.

Hypothyroidism:

Increased risk of respiratory depression and prolonged central nervous system depression.

CYP2D6 metabolism:

Codeine is metabolised by the liver enzyme CYP2D6 into morphine, its active metabolite. If a patient has a deficiency or is completely lacking this enzyme an adequate analgesic effect will not be obtained. Estimates indicate that up to 7 % of the Caucasian population may have this deficiency. However, if the patient is an extensive or ultra-rapid metaboliser there is an increased risk of developing side effects of opioid toxicity even at commonly prescribed doses. These patients convert codeine into morphine rapidly resulting in higher-than-expected serum morphine levels.

General symptoms of opioid toxicity include confusion, somnolence, shallow breathing, small pupils, nausea, vomiting, constipation, and lack of appetite. In severe cases this may include symptoms of circulatory and respiratory depression, which may be life-threatening and very rarely fatal.

Estimates of prevalence of ultra-rapid metabolisers in different populations are summarised below:

Population	Prevalence %
African/Ethiopian	29 %
African American	3,4 % to 6,5 %
Asian	1,2 % to 2 %
Caucasian	3,6 % to 6,5 %
Greek	6,0 %
Hungarian	1,9 %
Northern European	1 % to 2 %

Children:

Post-operative use in children:

There have been reports in the published literature that codeine given post-operatively in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, led to rare, but life-threatening, adverse events including death (see also section 4.3). All children received doses of codeine that were within the appropriate dose range; however, there was evidence that these children were either ultra-rapid or extensive metabolisers in their ability to metabolise codeine to morphine.

Children with compromised respiratory function:

Codeine is not recommended for use in children in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma, or extensive surgical procedures. These factors may worsen symptoms of morphine toxicity.

Pregnancy:

Regular use of NSAIDs such as IBUPAIN FORTE during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus *in utero*, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

Use of NSAIDs, including the ibuprofen in IBUPAIN FORTE, at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation. Complications of prolonged oligohydramnios may, for example, include limb contractures and delayed lung maturation. In some post-marketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.
Consider ultrasound monitoring of amniotic fluid if a patient was exposed to IBUPAIN FORTE treatment for more than 48 hours after 20 weeks gestation. Discontinue IBUPAIN FORTE and follow up according to clinical practice (see sections 4.3 and 4.6).

General:

IBUPAIN FORTE should be used with caution in the following:

- Acute abdominal conditions - diagnosis or clinical course may be obscured.
- Cardiac arrhythmias – may be induced or exacerbated.
- Recent gastrointestinal tract surgery.
- Adrenocortical insufficiency.
- Prostatic hypertrophy, obstruction, urethral stricture, or recent urinary tract surgery - as urinary retention may be precipitated by IBUPAIN FORTE.
- Anaemia – may be exacerbated.
- Patients who are receiving coumarin anticoagulants (see section 4.5).

4.5 Interaction with other medicines and other forms of interaction

IBUPAIN FORTE should not be taken with other medicines containing paracetamol, ibuprofen, acetylsalicylic acid, salicylates or with any other anti-inflammatory drugs (NSAIDs) unless under a doctor's instruction.

Ibuprofen:

Acetylsalicylic acid:

Concomitant administration of ibuprofen and acetylsalicylic acid (aspirin) is not generally recommended because of the potential of increased adverse effects.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardio-protective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1).

Corticosteroids:

Increased risk of gastrointestinal perforation, ulceration, or bleeding (PUBs) (see section 4.4).

Anticoagulants:

IBUPAIN FORTE may enhance the effects of anticoagulants, such as warfarin (see section 4.4).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs):

Increased risk of gastrointestinal bleeding (see section 4.4).

Alcohol, bisphosphonates, and pentoxifylline (oxpentifylline):

Concomitant administration with ibuprofen may increase the risk of NSAID-associated gastrointestinal bleeding and ulceration.

Other NSAIDs including cyclooxygenase-2 selective inhibitors:

Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects (see section 4.4).

Anti-hypertensives (ACE inhibitors and angiotensin II antagonists) and diuretics:

NSAIDs may diminish the effect of these medicines. In some patients with compromised renal function (e.g., dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor or angiotensin II antagonist and agents that inhibit cyclooxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking a coxib concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides:

NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium:

Decreased elimination of lithium.

Methotrexate:

Decreased elimination of methotrexate.

Ciclosporin:

Increased risk of nephrotoxicity.

Moclobemide:

Concomitant administration with NSAIDs may enhance the effects of the NSAID.

Tacrolimus:

Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine:

Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Phenytoin:

Concomitant administration of ibuprofen and phenytoin may enhance the effects of phenytoin.

Quinolone antibiotics:

Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Mifepristone:

NSAIDs should not be used for 8 – 12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Sulfonylureas:

Concomitant administration of ibuprofen and sulfonylureas may enhance the effects of sulfonylureas.

Paracetamol:

- Probenecid inhibits binding of paracetamol to glucuronic acid and thus leads to a reduction in the paracetamol clearance by about a factor of 2. During concomitant administration of probenecid, the paracetamol dose should be reduced.
- Special caution is advised during the concomitant use of medicines that lead to enzyme induction.
- Special caution is advised during the concomitant use of potentially hepatotoxic substances.
- Concomitant use of paracetamol and zidovudine increases the tendency to develop neutropenia.
- Cholestyramine reduces the absorption of paracetamol.
- Concomitant use of agents that lead to an acceleration of gastric emptying, such as metoclopramide or domperidone causes an acceleration of the uptake and the onset of action of paracetamol.
- Concomitant use of agents which slow the gastric emptying, may delay absorption and onset of action of paracetamol.
- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol, with increased risk of bleeding.

Codeine:

- Concomitant intake of MAOIs can increase central nervous system effects and other side effects to an unforeseeable extent. IBUPAIN FORTE should not be used until two weeks after the end of treatment with MAO inhibitors (see section 4.3).
- Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants, including alcohol, anaesthetics, hydroxyzine (anxiolytics), hypnotics, sedatives, tricyclic antidepressants or antipsychotics and phenothiazines, can increase the risk of respiratory depression, profound sedation and hypotension (see section 4.4).
- Concomitant administration of IBUPAIN FORTE and antihistamines and antihypertensives may enhance the sedative and respiratory depressant effect.
- Alcohol should be avoided during treatment with IBUPAIN FORTE as the psychomotor performance can be significantly reduced.
- Cimetidine and other medicines which are known to influence the hepatic metabolism, may enhance the effect of IBUPAIN FORTE.
- Concurrent use of codeine with antidiarrhoeal and antiperistaltic agents such as loperamide and kaolin may increase the risk of severe constipation.
- Concomitant use of antimuscarinics or medications with muscarinic action, e.g. atropine and some antidepressants may result in an increased risk of severe constipation which may lead to paralytic ileus and/or urinary retention.
- The respiratory depressant effect caused by neuromuscular blocking agents may be additive to the central respiratory depressant effects of opioid analgesics.
- Quinidine can inhibit the analgesic effect of codeine.
- Codeine may delay the absorption of mexiletine and thus reduce the antiarrhythmic effect of the latter.
- Codeine may antagonise the gastrointestinal effects of metoclopramide, cisapride, and domperidone.
- Naloxone antagonises the analgesic, CNS and respiratory depressant effects of opioid analgesics. Naltrexone also blocks the therapeutic effect of opioids.
- Opioid analgesics interfere with a number of laboratory tests including plasma amylase, lipase, bilirubin, alkaline phosphatase, lactate dehydrogenase, alanine aminotransferase and aspartate aminotransferase. Opioids may also interfere with gastric emptying studies as they delay gastric emptying and with hepatobiliary imaging using technetium Tc 99m disofenin as opioid treatment may cause constriction of the sphincter of Oddi and increase biliary tract pressure.

4.6 Fertility, pregnancy, and lactation

Due to the presence of ibuprofen:

IBUPAIN FORTE is contraindicated during pregnancy and breastfeeding (see sections 4.3 and 4.4).
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1 %, up to approximately 1,5 %. The risk is believed to increase with dose and duration of therapy.

In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

During the second or third trimester of pregnancy, NSAIDs including ibuprofen may cause foetal renal dysfunction which may result in reduction of amniotic fluid volume or oligohydramnios in severe cases. Published studies and post-marketing reports describe maternal NSAID use at about 20 weeks gestation or later in pregnancy associated with foetal renal dysfunction leading to oligohydramnios, and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. In many cases, but not all, the decrease in amniotic fluid was transient and reversible with cessation of the medicine. There have been a limited number of case reports of maternal NSAID use and neonatal renal dysfunction without oligohydramnios, some of which were irreversible. Some cases of neonatal renal dysfunction required treatment with invasive procedures, such as exchange transfusion or dialysis. Methodological limitations of these post-marketing studies and reports include lack of a control group; limited information regarding dose, duration, and timing of drug exposure; and concomitant use of other medications. These limitations preclude establishing a reliable estimate of the risk of adverse foetal and neonatal outcomes with maternal NSAID use. Because the published safety data on neonatal outcomes involved mostly preterm infants, the generalisability of certain reported risks to the full-term infant exposed to NSAIDs through maternal use is uncertain.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)
- possible prolongation of bleeding time, an antiaggregating effect which may occur even at very low doses
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, IBUPAIN FORTE is contraindicated during pregnancy (see section 4.3 and 4.4).

Due to the presence of codeine:

An association between abnormalities of the respiratory tract and the use of codeine during the first three months of pregnancy was found in humans. Evidence for other malformations was also found in epidemiological studies with narcotic analgesics, including codeine.

In case of imminent birth or preterm birth, the use of codeine is contraindicated since codeine crosses the placental barrier and can cause neonatal respiratory depression.

During long-term use of codeine an opioid dependence of the foetus can develop. Withdrawal symptoms in the new-born after repeated use of codeine in the last trimester of pregnancy were reported.

Due to the presence of paracetamol:

A large amount of data on pregnant women indicate neither malformative, nor foeto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol *in utero* show inconclusive results.

Breastfeeding

IBUPAIN FORTE should not be used during breastfeeding (see section 4.3).

At normal therapeutic doses codeine and its active metabolite may be present in breast milk at very low doses and is unlikely to adversely affect the breast fed infant. However, if the patient is an ultra-rapid metaboliser of CYP2D6, higher levels of the active metabolite, morphine, may be present in breast milk and on very rare occasions may result in symptoms of opioid toxicity in the infant, which may be fatal.

Fertility

The use of ibuprofen may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of IBUPAIN FORTE should be considered.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue, and visual disturbances are possible after intake of IBUPAIN FORTE (see section 4.8). If affected, patients should not drive or operate machinery. IBUPAIN FORTE can also impair cognitive function and can affect a patient's ability to drive safely. Advise patients that they should not engage in the above activities until they are aware of the measure to which IBUPAIN FORTE affects them.

4.8 Undesirable effects

a. Summary of the safety profile

The most commonly observed adverse effects are gastrointestinal in nature.

b. Tabulated summary of adverse reactions

Ibuprofen:

Infections and infestations:

Less frequent:	Rhinitis and aseptic meningitis (especially in patients with existing autoimmune disorders, such as systemic lupus erythematosus and mixed connective tissue disease) with symptoms of stiff neck, headache, nausea, vomiting, fever, or disorientation (see section 4.4).

Blood and the lymphatic system disorders:

Less frequent:	Agranulocytosis, thrombocytopenia, leukopenia, neutropenia, pancytopenia, aplastic anaemia, haemolytic anaemia, eosinophilia.
Frequency unknown:	Reversible inhibition of platelet aggregation.

Immune system disorders:

Frequent:	Rashes (see section 4.4).
Less frequent:	Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reactions and anaphylaxis (which could include facial, tongue and throat swelling, tachycardia, hypotension or severe shock) (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely exfoliative and bullous dermatoses (including Stevens- Johnson syndrome, toxic epidermal necrolysis and erythema multiforme). Hypersensitivity reactions may also include hepatotoxicity and aseptic meningitis.
Frequency not known:	Fever.

Metabolism and nutrition disorders

Frequency not known:	Hypokalaemia (see section 4.8 (c) below).

Psychiatric disorders:

Less frequent:	Insomnia, anxiety, depression, confusion state, hallucination.

Nervous system disorders:

Frequent:	Dizziness.
Less frequent:	Nervousness, drowsiness, headache, optic neuritis, paraesthesia, somnolence.

Eye disorders:

Less frequent:	Visual impairment and toxic optic neuropathy, visual disturbances.

Ear and labyrinth disorders:

Less frequent:	Hearing impairment, tinnitus, and vertigo.

Cardiac disorders:

Less frequent:	Cardiac failure may be precipitated in compromised patients, angina pectoris, cardiac arrhythmias, oedema.

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high dose (2400 mg daily), and in long term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

Vascular disorders:

Less frequent:	Hypertension.

Respiratory, thoracic, and mediastinal disorders:

Frequency not known:	Respiratory tract reactivity comprising asthma, bronchospasm, or dyspnoea.

Gastrointestinal disorders:

The most commonly observed adverse events are gastrointestinal in nature.

Frequent:	Peptic ulcers, perforation, or gastrointestinal bleeding, sometimes fatal. Dyspepsia, nausea, vomiting, diarrhoea, abdominal cramps and pain, bloating, flatulence, constipation, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.
Less frequent:	Pancreatitis.
Frequency not known:	Gastrointestinal discomfort.

Hepatobiliary disorders:

Less frequent:	Hepatic function abnormal, hepatic failure, hepatitis, and jaundice.

Skin and subcutaneous tissue disorders:

Less frequent:	Skin rash, pruritus. Bullous reactions, including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis, photosensitivity reaction, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (see section 4.4).
Frequency not known:	Acute generalised exanthematous pustulosis (AGEP).

Renal and urinary disorders:

Less frequent:	Impairment of renal function, acute reversible renal failure (Especially in long-term use, associated with increased serum urea and oedema. Also includes papillary necrosis).
Frequency not known:	Renal tubular acidosis (see section 4.8(c) below), interstitial nephritis, nephrotic syndrome.

General disorders and administration site conditions:

Less frequent:	Malaise, fatigue.
Frequency not known:	Hyperhidrosis, irritability.

Paracetamol:

Blood and lymphatic system disorders:

Less frequent:	Haematological reactions (including thrombocytopenia, leukopenia, pancytopenia, neutropenia, and agranulocytosis.

Immune system disorders:

Less frequent:	Hypersensitivity. Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema. Very rare cases of serious skin reactions have been reported (see section 4.4). Anaphylactic reaction.

Respiratory, thoracic, and mediastinal disorders:

Less frequent:	Bronchospasm*.

*There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Gastrointestinal disorders:

Frequency not known:	Pancreatitis.

Hepatobiliary disorders:

Less frequent:	Hepatic enzyme increase, hepatic dysfunction.

Skin and subcutaneous tissue disorders:

Less frequent:	Rash (usually erythematous or urticarial but sometimes more serious and accompanied by fever and mucosal lesions – see section 4.4), pruritus, erythema, urticaria.

Very rare cases of serious skin reactions have been reported [including drug-induced Stevens- Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalised Exanthematous Pustulosis (AGEP), Fixed Drug Eruptions (FDE), and Drug-induced Hypersensitivity Syndrome (DIHS) – see section 4.4].

Renal and urinary disorders:

Less frequent:	Renal colic, renal failure.

Codeine phosphate:

Metabolism and nutrition disorders:

Frequency not known:	Decreased appetite.

Psychiatric disorders:

Less frequent:	Hallucinations, dysphoria, euphoria, mood changes, restlessness, confusion.
Frequency not known:	Nightmares.

Nervous system disorders:

Frequent:	Drowsiness, dizziness, seizures, addiction, tolerance, dependence, headache, vertigo, malaise, sleep disturbances.
Frequency not known:	Convulsion, intracranial pressure increased, dyskinesia, confusion, restlessness.

Eye disorders:

Less frequent:	Miosis, visual disturbances.
Frequency not known:	Vision blurred, diplopia.

Cardiac disorders:

Less frequent:	Bradycardia, palpitations, tachycardia.

Vascular disorders:

Less frequent:	Postural hypotension, hypothermia, facial flushing.

Respiratory, thoracic, and mediastinal disorders:

Less frequent:	Respiratory depression.
Frequency not known:	Cough suppression.

Gastrointestinal disorders:

Frequent:	Nausea, vomiting, constipation, pancreatitis.
Less frequent:	Dry mouth.

Hepatobiliary disorders:

Less frequent:	Biliary spasm, liver disorder.
Frequency not known:	Biliary colic.

Skin and subcutaneous tissue disorders:

Less frequent:	Sweating, urticaria, pruritus, rashes.
Frequency not known:	Facial flushing.

Musculoskeletal and connective tissue disorders:

Frequency not known:	Muscle rigidity.

Renal and urinary disorders:

Less frequent:	Micturition difficulties, ureteric spasm or retention, dysuria (Increased frequency, decrease in amount).

Reproductive system and breast disorders:

Frequency not known:	Decreased libido or potency.

General disorders and administrative site conditions:

Frequency not known:	Hypothermia.

Investigations:

Less frequent:	Haemoglobin decreased.

c. Description of selected adverse reactions

Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses due to dependence on the codeine component.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Paracetamol:

Prompt treatment is essential.

In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Symptoms:

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 to 10 g/day) of paracetamol for several days, in the elderly, young children, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of medicines that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine. In these cases, an overdose can be fatal.

In general, symptoms occur within 24 hours: pallor, nausea, vomiting, anorexia, and abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion of paracetamol, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentrations and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma, and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported. Cerebral oedema and non-specific myocardial depression have occurred.

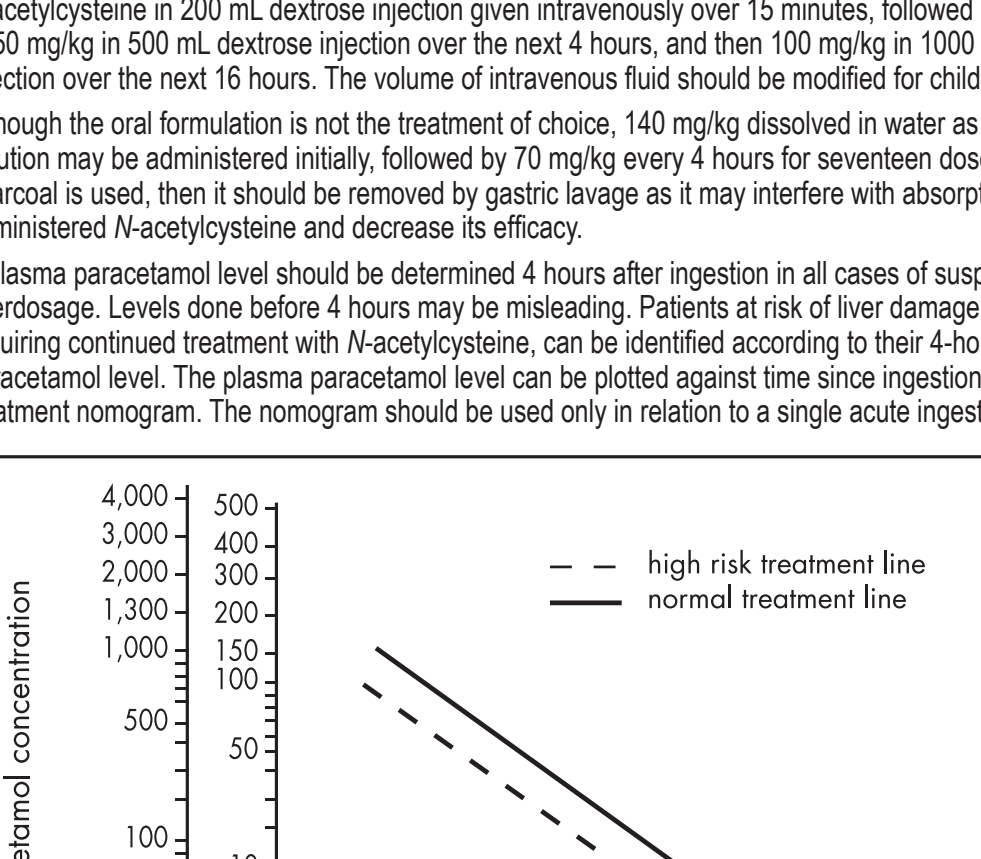
Treatment of overdose:

Although evidence is limited, it is recommended that an adult who has ingested 5 to 10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding 4 hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose, endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible, preferably within 8 hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg *N*-acetylcysteine in 200 mL dextrose injection given intravenously over 15 minutes, followed by an infusion of 50 mg/kg in 500 mL dextrose injection over the next 4 hours, and then 100 mg/kg in 1000 mL dextrose injection over the next 16 hours. The volume of intravenous fluid should be modified for children.

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water as a 5 % solution may be administered initially, followed by 70 mg/kg every 4 hours for seventeen doses. If activated charcoal is used, then it should be removed by gastric lavage as it may interfere with absorption of orally administered *N*-acetylcysteine and decrease its efficacy.

A plasma paracetamol level should be determined 4 hours after ingestion in all cases of suspected overdosage. Levels done before 4 hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with *N*-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the treatment nomogram. The nomogram should be used only in relation to a single acute ingestion.



Adapted from Smilkstein *et al*., Ann. Emerg.Med., 1991, 20, 1059

Those whose plasma paracetamol levels are above the "normal treatment line", should continue *N*-acetylcysteine treatment with 100 mg/kg IV over 16 hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line".
Prothrombin index correlates best with survival.

Monitor all patients with significant ingestions for at least 96 hours.

Ibuprofen:

Symptoms:

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

In serious poisoning metabolic acidosis may occur and the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur.
Prolonged use at higher than recommended doses may result in severe hypokalaemia and renal tubular acidosis. Symptoms may include reduced level of consciousness and generalised weakness (see section 4.4 and section 4.8).
Exacerbation of asthma is possible in asthmatics.

Therapeutic measure:

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life- threatening overdose.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam.
Other measures may be indicated by the patient's clinical condition.

Codeine:

Symptoms:

Codeine overdose may result in central nervous system and respiratory depression with hypoxia, hypotension, shock, gastric hypomotility with ileus, non-cardiogenic pulmonary oedema. Nausea and vomiting are prominent features. The opiate intoxication syndrome is described as a triad of depressed level of consciousness, miotic pupils, and decreased respirations.

Management:

Treatment is based more on clinical presentation than on specific laboratory data, except when complications have occurred.
Plasma codeine levels are not clinically useful. Support the respiratory and cardiovascular function. Monitor arterial blood gases and/or pulse oximetry, pulmonary function tests, and chest x-ray in patients with significant exposure.
Ipecac-induced emesis is not recommended because of the potential for CNS depression and seizures. Consider pre-hospital administration of activated charcoal as aqueous slurry in patients with a potentially toxic ingestion who are awake and able to protect their airway.
Activated charcoal is most effective when administered within one hour of ingestion. Use a minimum of 240 mL of water per 30 g charcoal.
Optimum dose has not been established, but the usual dose is 25 to 100 g in adults and adolescents; 25 to 50 g in children aged 1 to 12 years (or 0,5 to 1 g/kg body weight); and 1 g/kg in infants up to 1 year old.

Consider naloxone as antidote in patients with decreased level of consciousness. The most frequently recommended initial naloxone dose for codeine overdose is 0,4 to 2 mg intravenous bolus in both children and adults.

This dose can also be given subcutaneously in the absence of intravenous access or intratracheally.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological classification: A 2.8 Analgesic combinations
Pharmacotherapeutic group: Codeine and other non-opioid analgesics
ATC code: N02AJ09

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic effects. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

Ibuprofen has analgesic, antipyretic and anti-inflammatory activities. Ibuprofen is a non- steroidal anti-inflammatory medicine that, in the conventional animal-experiment inflammation models, has proven to be effective via prostaglandin synthesis inhibition. In humans, ibuprofen reduces inflammatory-related pain, swelling and fever. Furthermore, ibuprofen reversibly inhibits ADP- and collagen-induced platelet aggregation.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low-dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 hours before or within 30 minutes after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardio-protective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 4.5).

Codeine is a centrally acting weak analgesic. Codeine exerts its effect through µ opioid receptors, although codeine has low affinity for these receptors, and its analgesic effect is due to its conversion to morphine. Codeine, particularly in combination with other analgesics such as paracetamol, has been shown to be effective in acute nociceptive pain.

5.2 Pharmacokinetic properties

Paracetamol:

Paracetamol is rapidly absorbed from the upper gastrointestinal tract after oral administration. Paracetamol is metabolised in the liver primarily by conjugation. Paracetamol has a half-life of 1 to 4 hours, time to peak concentration of 0,5 to 2 hours, time to peak effect of 1 to 3 hours and the duration of action of 3 to 4 hours. Paracetamol is renally excreted primarily as metabolites and 3 % of a dose may be excreted unchanged.

Ibuprofen:

Rapidly absorbed after oral administration. Onset of action for pain relief is 30 minutes and the time for peak effect for fever is 2 to 4 hours. The half-life of ibuprofen is about 2 hours and the duration of action for fever is 6 to 8 hours or more and is 4 to 6 hours for pain. More than 90 % of an ingested dose is excreted in the urine as metabolites or their conjugates.

Codeine:

Readily absorbed from the gastrointestinal tract. Half-life is 2,5 to 4 hours. Codeine is metabolised in the liver. The cytochrome P450 enzyme 2D6 converts codeine to morphine, one of its metabolites. About 10 % of the dose is demethylated to morphine. Onset of action is 30 to 45 minutes. The time to peak effect is 1 to 2 hours. Duration of action is 4 hours. Codeine is eliminated via the kidneys.

5.3 Preclinical safety data

Paracetamol:

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

Ibuprofen and Codeine:

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule fill: pregelatinised starch, microcrystalline cellulose, purified talc.
Capsule shell: erythrosine, red iron oxide, titanium dioxide, yellow iron oxide, gelatine, indigo carmine, quinolone yellow.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Keep in a dry place at or below 25 °C. Protect from light.

6.5 Nature and contents of container

White opaque polypropylene securitainers with clip-on, low-density or medium-density or high-density polyethylene pilfer proof seals with 10, 30, 60, 100 or 500 capsules.
Clear PVC or Tristar blisters sealed with aluminium foil with 10, 30, 60, 100 or 500 capsules packed into a cardboard carton.
Sealed aluminium layflat patient ready bags with LDPE ribbed zipper with 30, 60 or 100 capsules.
Amber glass containers with black, hard plastic (polypropylene) screw caps with expanded LDPC inner seals with 30, 60 or 100 capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Kiara Health (Pty) Ltd
72 Steel Road, Spartan,
Kempton Park, 1619
South Africa

8. REGISTRATION NUMBER

37/2.8/0060

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03 June 2005

10. DATE OF REVISION OF THE TEXT

May 2024

KIARA

51010856
V2(05/2024)
1023IBUPF-007

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

IBUPAIN® FORTE (capsules)

Ibuprofen, codeine phosphate, and paracetamol.
Sugar free.

Read all of this leaflet carefully because it contains important information for you.
IBUPAIN FORTE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use IBUPAIN FORTE carefully to get the best results from it.
• Keep this leaflet. You may need to read it again.
• Do not share IBUPAIN FORTE with any other person.
• Ask your healthcare provider or pharmacist if you need more information or advice.
• Please consult your doctor if your symptoms worsen or do not improve within 5 days of treatment.

What is in this leaflet
1. What IBUPAIN FORTE is and what it is used for
2. What you need to know before you take IBUPAIN FORTE
3. How to take IBUPAIN FORTE
4. Possible side effects
5. How to store IBUPAIN FORTE
6. Contents of the pack and other information.

1. What IBUPAIN FORTE is and what it is used for
IBUPAIN FORTE is used for mild to moderate pain caused by inflammation, with or without fever.

2. What you need to know before you take IBUPAIN FORTE
Do not take IBUPAIN FORTE:
• if you are hypersensitive (allergic) to ibuprofen, paracetamol, or codeine or any of the other ingredients of IBUPAIN FORTE (listed in section 6).
• if you have previously had an allergic reaction to aspirin or other pain/inflammation medication.
• if you have difficulty breathing such as seen with emphysema, especially in the presence of blue discolouration of the skin or lips and excessive phlegm, after an operation on the gall bladder or bile ducts, if you suffer from acute alcoholism, convulsive disorders (or epilepsy), if you had a head injury or if you have been diagnosed with raised pressure inside the skull, or if you have heart failure secondary to a chronic lung disease (see **Warnings and precautions**).
• if you are on medication called Monoamine Oxidase Inhibitors (MAOIs) that is used to treat depression or have taken some within the last 14 days.
• if you have diarrhoea due to inflammation in your intestines which may be a result of antibiotic use.
• if you suffer from liver or kidney impairment.
• if you have, or have a history of, a stomach ulcer or bleeding from the stomach. This could be due to previous use of pain/inflammation medication.
• if you have a heart or blood vessel disease.
• if you have uncontrolled asthma or breathing difficulties (tightness of the chest).
• if you have nasal polyps due to aspirin-induced asthma.
• if you have a bleeding disorder.
• if you have heart failure.
• if you are younger than 18 years of age and you are being treated for pain after surgery to remove your tonsils and/or adenoids, as you may have an increased risk of developing serious and life-threatening side effects.
• if you are an ultra-rapid CYP2D6 metaboliser. This is a liver enzyme that metabolises medicines (see **Warnings and precautions**).
• if you are pregnant, due to risk of kidney dysfunction in the foetus (see **Pregnancy, breastfeeding, and fertility**).
• if you are breastfeeding.
• if you suffer from chronic constipation.

Warnings and precautions

IBUPAIN FORTE contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison centre must be contacted immediately.
IBUPAIN FORTE contains codeine, which is an opioid medicine. Repeated use of IBUPAIN FORTE may result in you becoming accustomed to it (needing to take higher doses). Repeated use of IBUPAIN FORTE may also lead to dependence, abuse, and addiction, which may result in life-threatening overdose.
If you are taking IBUPAIN FORTE for longer than the recommended time or at higher than recommended doses, you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see Possible side effects).
If you experience any of the following signs whilst taking IBUPAIN FORTE, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted:
• You need to take this medicine for longer than advised
• You need to take more than the recommended dose
• You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'
• You have made repeated, unsuccessful attempts to quit or control the use of this medicine
• When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects').

Dosages in excess of those recommended may cause severe liver damage.

The side effects of IBUPAIN FORTE can be minimised by taking the lowest effective dose for the shortest duration.

IBUPAIN FORTE is for short-term use and is not recommended for use beyond 5 days. During 20 weeks or later in pregnancy, IBUPAIN may cause kidney dysfunction in newborns (see **Pregnancy, breastfeeding, and fertility**).

Take special care with IBUPAIN FORTE:
IBUPAIN FORTE may trigger asthma or allergic reactions. If you suffer from or have a history of asthma or allergic diseases, you should avoid using IBUPAIN FORTE.

You must avoid taking IBUPAIN FORTE in combination with other medicines that are used to treat inflammation (known as non-steroidal anti-inflammatory medicines or NSAIDs) such as diclofenac or celecoxib.

If you have a history of high blood pressure, you will require careful monitoring while taking IBUPAIN FORTE. It may cause fluid retention and thus may lead to heart failure in patients whose heart function has been compromised.

The ibuprofen in IBUPAIN FORTE carries a small increased risk of blood clot formation in the arteries leading to a heart attack or stroke, especially if used in high doses (2400 mg/day). Lower doses (equal to or less than 1200 mg/day) do not seem to carry the same risk. If you previously had a heart attack or stroke, please speak to your doctor before taking IBUPAIN FORTE. You should also discuss its use with your doctor if you have uncontrolled high blood pressure, coronary artery disease (also known as ischaemic heart disease), or poor blood circulation due to blockage of your arteries.

If you have uncontrolled high blood pressure, high blood lipid or cholesterol levels, diabetes, or if you smoke, you may be at an increased risk of adverse cardiac events, especially if you use IBUPAIN FORTE over the long term or in a high dose.

Gastrointestinal bleeding, ulceration, or perforation, which can be fatal, has been reported with IBUPAIN FORTE at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.

This risk of gastrointestinal side effects is higher with increasing doses, in the elderly, or if you have a history of stomach ulcers.

You need to start treatment with IBUPAIN FORTE on the lowest possible dose. Ask your doctor or pharmacist about additional medication that can prevent gastrointestinal side effects if you are prone to stomach ulcers.

You should contact your doctor if you notice any abdominal side effects (especially bleeding which may present with black, tarry stools). You should stop taking IBUPAIN FORTE if you notice bleeding or suspect that you have a stomach ulcer. Before you take IBUPAIN FORTE, please obtain advice from your doctor or pharmacist if you have been diagnosed with ulcerative colitis, Crohn's disease, hiatus hernia, acid reflux, or abnormal blood vessel formation.

NSAIDs, such as the ibuprofen in IBUPAIN FORTE, may cause kidney failure, especially in people with impaired kidney function, impaired heart function, abnormal liver function, and in those taking diuretics (water tablets) and in the elderly. It will be necessary for your doctor to monitor your kidney function in these instances. Extra care is required in dehydrated children and adolescents.

IBUPAIN FORTE should be stopped at the first appearance of skin rash, sores in your mouth, or any other sign of an allergic reaction. Serious skin reactions, which can be fatal, have been reported (see **Possible side effects**). If you develop a fever or swelling of the lymph glands while taking IBUPAIN FORTE, stop taking IBUPAIN FORTE and immediately report to your doctor.

IBUPAIN FORTE may hide signs of infections such as fever and pain. It is therefore possible that IBUPAIN FORTE may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed with pneumonia caused by bacteria and with bacterial skin infections related to chickenpox. If you take IBUPAIN FORTE while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Elderly patients have an increased frequency of side effects, especially stomach ulcers and bleeding, which may result in death. IBUPAIN FORTE can also result in breathing difficulties in the elderly. You should not combine IBUPAIN FORTE with other medicines containing codeine.

Long-term and habitual use of pain medicines, and especially combinations of different pain medicines, including IBUPAIN FORTE, can result in permanent kidney damage and the risk of kidney failure.

Long-term, inappropriate use of high doses of analgesics, including IBUPAIN FORTE, may cause headaches, which may not be treated by increasing doses of the medicine.

If you have problems with your gallbladder or have gallstones, you should use IBUPAIN FORTE with caution, as it may cause spasm of the biliary tract, which will result in abdominal pain, which may come and go.

You should take special care if you have the tendency to misuse medicine or have a drug problem. You should not take IBUPAIN FORTE with other codeine-containing medicines. You may develop tolerance (having to take increased doses to obtain the same effect), physical, and psychological dependence and opioid use disorder if you repeatedly take codeine-containing medicines. Abuse or intentional misuse of IBUPAIN FORTE may result in overdose and/or death (see boxed warning above).

Taking alcohol with IBUPAIN FORTE can increase your risk for liver toxicity.

If you suffer a head injury while taking IBUPAIN FORTE, please inform your doctor or the personnel at the emergency care centre that you are using a codeine-containing medicine. IBUPAIN FORTE may increase your risk of respiratory depression and of developing raised intracranial (inside the skull) pressure. It may also cause sedation and changes to how your pupils react to light, which may obscure the clinical course of your injury.

If you have an underactive thyroid gland, you have an increased risk of experiencing breathing problems and central nervous system depression (decreased heart rate and loss of consciousness due to inhibited brain activity) with the use of IBUPAIN FORTE.

If you know that some of your liver enzymes (known as enzyme CYP2D6) metabolise medicines very rapidly, you should not take IBUPAIN FORTE as this can be very dangerous. You might experience symptoms such as confusion, sleepiness, shallow breathing, small pupils, nausea, vomiting, constipation and lack of appetite, and difficulty breathing due to the rapid conversion of codeine to morphine in the body.

You should not take IBUPAIN FORTE if you are pregnant or breastfeeding your baby (see **Do not take IBUPAIN FORTE** and **Pregnancy, breastfeeding, and fertility**). Taking IBUPAIN FORTE during pregnancy may harm your baby.

If any of the following applies to you, please discuss the use of IBUPAIN FORTE with your doctor or pharmacist before you start taking it:
• you have any stomach condition as the diagnosis may be obscured.
• you have an abnormal heart rhythm (known as arrhythmia).
• you recently had stomach surgery.
• you have adrenocortical insufficiency (adrenal gland disorder).
• you have prostate problems or have recently had urinary tract surgery.
• you have a blood condition called anaemia (with low red blood cell counts), which could be made worse.

Children and adolescents:
IBUPAIN FORTE should not be used in children below the age of 12 years.

Do not take IBUPAIN FORTE if you are younger than 18 years and you are being treated for pain after surgery to remove your tonsils and/or adenoids, as there is an increased risk of developing serious and fatal side effects.

Do not give IBUPAIN FORTE to children in whom lung function may be compromised (for example, by any disease that affects the neuromuscular system, severe heart or lung disorders, upper respiratory tract or lung infections, multiple trauma, or extensive surgical procedures).

Ensure that children and adolescents are not dehydrated when taking IBUPAIN FORTE, as dehydration may increase the risk of kidney impairment.

Other medicines and IBUPAIN FORTE
Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Please discuss the use of the following medicines or substances in combination with IBUPAIN FORTE with your doctor or pharmacist before you start taking it:
• aspirin, corticosteroids (e.g., prednisone), methotrexate, ciclosporin, other non-steroidal anti-inflammatory medicines (e.g., diclofenac, meloxicam, celecoxib, etc.)
• blood thinning tablets (e.g., warfarin) or antiplatelet medicines (e.g., low-dose aspirin, clopidogrel)
• antidepressant medicines known as serotonin reuptake inhibitors such as citalopram, paroxetine, fluoxetine
• alcohol
• bisphosphates to treat osteoporosis such as alendronate or risedronate
• pentoxifylline for the treatment of muscle cramps in people with peripheral arterial disease
• medicines to treat high blood pressure known as ACE-inhibitors (e.g., perindopril, enalapril) or angiotensin receptor blockers (e.g., losartan, valsartan), or "water tablets"
• heart medication such as digoxin
• lithium (for mood disorders)
• tacrolimus (used to prevent organ rejection following a transplant)
• zidovudine (AIDS medication)
• phenytoin for epilepsy
• antibiotics like ciprofloxacin, moxifloxacin etc.
• mifepristone (used to end a pregnancy)
• sulfonylureas (such as gliclazide, glipizide, glimepiride) to treat diabetes
• probenecid used in the treatment of gout
• cholesterol medication called cholestyramine
• medicines to treat nausea and vomiting such as metoclopramide, domperidone
• medicines that delay emptying of the stomach such as ranitidine or sucralfate
• antidepressants called monoamine oxidase inhibitors (e.g. moclobemide, selegiline, etc.) (see **Do not take IBUPAIN FORTE**)
• sedative or sleep-inducing medicines such as benzodiazepines (e.g., alprazolam), medicines to treat anxiety, antipsychotics (e.g., quetiapine, risperidone, olanzapine), antihistamines, or tricyclic antidepressants (such as amitriptyline)
• cimetidine (used to treat stomach ulcers and indigestion)
• loperamide and kaolin (medicines to treat diarrhoea)
• medicines which are used as premedication before operations, or to treat gut or bladder problems, such as atropine, solifenacin, oxybutynin
• quinidine or mexiletine (used to treat abnormal heart rhythms)
• cisapride (used to treat heartburn)
• naloxone (used to treat opioid overdose).

IBUPAIN FORTE can affect the results of laboratory tests. Tell the person doing the test that you are taking IBUPAIN FORTE.

IBUPAIN FORTE with food, drink, and alcohol
You should not drink alcohol while you are taking IBUPAIN FORTE. This is because alcohol can increase the risk of serious side effects.

Pregnancy, breastfeeding, and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking IBUPAIN FORTE.

You should not take IBUPAIN FORTE during pregnancy (see **Do not take IBUPAIN FORTE**). In early pregnancy, the ibuprofen may hamper implantation of the fertilised egg and the development of the embryo. Later in pregnancy, it may reduce the production of amniotic fluid and give rise to abnormal kidney and lung function in the growing foetus. If used near term, it may affect the baby's blood circulation and cause delayed or prolonged labour. Please speak to your doctor if you need more information.
IBUPAIN FORTE should not be used during breastfeeding (see **Do not take IBUPAIN FORTE**).

Driving and using machines
IBUPAIN FORTE can cause dizziness, drowsiness, tiredness, and visual disturbances. It may also impair your mental acuity and ability to concentrate and thus your ability to drive safely. You should not drive or operate machinery if you experience these effects.
It is not always possible to predict to what extent IBUPAIN FORTE may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which IBUPAIN FORTE affects you.

3. How to take IBUPAIN FORTE
Do not share your medicine with any other person.
Always take IBUPAIN FORTE exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.
Side effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see **Warnings and precautions: Take special care with IBUPAIN FORTE**).

IBUPAIN FORTE is not for children under twelve years of age.

Adults, the elderly and children over 12 years:
Take one (1) to two (2) capsules four (4) to six (6) hourly. Do not take more than six (6) capsules in 24 hours.

You should not take IBUPAIN FORTE for more than 5 days, and if you are not feeling better, you should see your doctor.

If you have liver or kidney problems, or Gilbert's syndrome (liver disorder), speak to your doctor or pharmacist, as you will need to take a lower dose and/or leave more time between doses.

The elderly are at higher risk of serious side effects, and therefore should use the lowest effective dose for the shortest possible duration. If you are elderly, you will need to be monitored often for gastrointestinal bleeding (e.g. stomach, intestine, etc.).

If you have the impression that the effect of IBUPAIN FORTE is too strong or too weak, tell your doctor or pharmacist.

If you take more IBUPAIN FORTE than you should
Prompt treatment is essential.
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

A delay in starting treatment for paracetamol overdose may mean that treatment is given too late to be effective. Paracetamol overdose can lead to liver damage and death. Elderly subjects, young children, patients with liver disease, alcoholic patients, malnourished patients, or patients taking other medicines at the same time, which have an effect on liver enzymes, are particularly at risk, after an overdose.

Symptoms of paracetamol overdosage usually occur within 24 hours and may include pallor (skin colour becoming pale), nausea, vomiting, anorexia, and abdominal pain. Afterwards, your condition may improve, however, mild stomach pain may continue, which could indicate that you have liver damage.

Ibuprofen overdose may cause the following symptoms: nausea, vomiting, stomach pain, or more rarely diarrhoea. Tinnitus (ringing in the ears), headache and gastrointestinal bleeding (severe stomach pains, blood in stool) are also possible. In more serious poisoning, symptoms may include dizziness, headache, drowsiness, excitation (feeling excited), disorientation, coma and convulsions. In serious poisoning, the following may occur: metabolic acidosis (high acid levels in the body), reduced blood clotting, worsening of asthma, kidney failure and liver failure may occur.

Codeine overdose may result in nausea, vomiting, hypoxia (not enough oxygen is circulated in the body), hypotension (low blood pressure, which can cause you to feel lightheaded or dizzy), shock and constipation. You may present with a lowered level of consciousness, reduced pupil size and slower breathing.

Your doctor will determine suitable treatment for your overdose.

If you forget to take IBUPAIN FORTE
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
IBUPAIN FORTE can have side effects.

Not all side effects reported for IBUPAIN FORTE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBUPAIN FORTE, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking IBUPAIN FORTE and tell your doctor immediately or go to the casualty department of your nearest hospital:
• swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty in swallowing and breathing.
• rash or itching.
• fainting.
• yellowing of the skin and eyes, also called jaundice.
• signs of intestinal bleeding such as: bright red faeces (stools/motions), black tarry stools (melaena), vomiting blood (haematemesis) or dark particles that look like coffee grounds.
• serious skin reactions which may include redness, hives (red itchy bumps), blisters, pustules, peeling of the skin and bleeding in the lips, eyes, mouth, nose and genitals (toxic epidermal necrolysis, Stevens-Johnson syndrome or erythema multiforme).
• a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
• a red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).
• skin becomes sensitive to light.
• muscle weakness or light-headedness. IBUPAIN FORTE, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see **Warnings and precautions**). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness (as mentioned).
• pancreatitis (inflammation of the pancreas) which may present as severe pain in the upper part of the stomach, going into your back, a swollen and tender belly, fever.
• seizures.
• meningitis or raised pressure within the head that may cause a stiff neck, headache, nausea, vomiting, fever or disorientation.
• any changes in vision, including blurred or double vision, as it may indicate inflammation of the optic nerve (eye nerve).
• heart failure that may present with swelling of the hands and feet or severe shortness of breath.
• asthma, wheezing or shortness of breath, or difficulty breathing.

These are all very serious side effects. If you have <u>any of</u> them, you may have had a serious reaction to IBUPAIN FORTE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
The following side effects were experienced frequently:
• stomach ulcers
• indigestion
• nausea
• vomiting
• diarrhoea
• abdominal cramps and pain
• bloating
• flatulence
• constipation
• mouth ulcers
• exacerbation of bowel inflammation and Crohn's disease
• gastritis
• drowsiness
• dizziness
• addiction (see **Warnings and precautions**)
• tolerance (see **Warnings and precautions**)
• dependence (see **Warnings and precautions**)
• headache
• vertigo (balance disturbances)
• malaise (general feeling of uneasiness)
• sleep disturbances.

The following side effects were experienced less frequently:
• runny nose
• blood disorders (lowered white blood cells that increases your risk of infections, decreased platelets that may lead to easy bruising or bleeding)
• anaemia as a result of low red blood cell counts leading to pallor, tiredness, and shortness of breath
• insomnia
• anxiety
• depression
• confusional state
• hallucination
• feeling depressed or sad or extremely happy for no particular reason
• mood changes
• restlessness
• nervousness
• pins and needles in hands and feet
• feeling tired
• narrowing of the pupil
• hearing impairment
• hearing sound when no external sound is present
• changes to your heartbeat
• high blood pressure
• dizziness when getting in the upright position
• feeling cold
• facial flushing
• dry mouth
• impairment of renal and liver function
• biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
• pain and difficulty in passing urine and a less frequent need to do so
• spasm of the urinary system
• fatigue.

The frequency of the following side effects are unknown:
• increased sweating
• irritability
• nightmares
• uncontrolled muscle movements
• suppression of cough
• decreased appetite
• muscle stiffness
• decreased libido or potency
• hypothermia.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of IBUPAIN FORTE. Suspected side effects can also be reported directly to the HCR via customercare@kiarahealth.com

5. How to store IBUPAIN FORTE
Keep in a dry place at or below 25 °C. Protect from light.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
Do not use after the expiry date stated on the label or container.

6. Contents of the pack and other information
What IBUPAIN FORTE capsules contains
The active substances are ibuprofen 200 mg, codeine phosphate 10 mg, and paracetamol 250 mg.
The other ingredients in the capsule are pregelatinised starch, microcrystalline cellulose, purified talc.
The capsule shells consist of erythrosine, red iron oxide, titanium dioxide, yellow iron oxide, gelatine, indigo carmine, quinolone yellow.

What IBUPAIN FORTE looks like and contents of the pack
IBUPAIN FORTE are size 0 capsules with a red body and dark green cap containing a free- flowing white powder.

IBUPAIN FORTE is packed in:
White opaque polypropylene securitainers with clip-on, low-density or medium-density or high-density polyethylene pilfer proof seals with 10, 30, 60, 100 or 500 capsules.
Clear PVC or Tristar blisters sealed with aluminium foil with 10, 30, 60, 100 or 500 capsules packed into a cardboard carton.
Sealed aluminium layflat patient ready bags with LDPE ribbed zipper with 30, 60 or 100 capsules.
Amber glass containers with black, hard plastic (polypropylene) screw caps with expanded LDPC inner seals with 30, 60 or 100 capsules.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
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South Africa

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Access to the corresponding Professional Information
To access the corresponding Professional Information, email customercare@kiarahealth.com

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS: S2

IBUPAIN® FORTE (kapsules)

Ibuprofeen, kodeïenfosfaat en parasetamol.
Suikervry.

Lees hierdie hele blaadjie sorgvuldig aangesien dit belangrike inligting vir u bevat.
IBUPAIN FORTE is sonder 'n doktersvoorskrif vir u beskikbaar om 'n geringe siekte te behandel. Nogtans moet u IBUPAIN FORTE steeds versigtig gebruik om die beste resultate daarmee te verkry
• Hou hierdie blaadjie. U mag nodig kry om dit weer te lees.
• Moenie IBUPAIN FORTE met enige ander persoon deel nie.
• Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
• Raadpleeg asseblief u dokter indien u simptome vererger of nie binne 5 dae van behandeling verbeter nie.

Wat in hierdie blaadjie is
1. Wat IBUPAIN FORTE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u IBUPAIN FORTE neem
3. Hoe om IBUPAIN FORTE te neem
4. Moontlike newe-effekte
5. Hoe om IBUPAIN FORTE te berg
6. Inhoud van die pakkie en ander inligting.

1. Wat IBUPAIN FORTE is en waarvoor dit gebruik word
IBUPAIN FORTE word vir geringe tot matige pyn veroorsaak deur inflammasie, met of sonder koors, gebruik.

2. Wat u moet weet voordat u IBUPAIN FORTE neem
Moenie IBUPAIN FORTE neem nie:
• indien u vir ibuprofeen, parasetamol of kodeïen of enige van die ander bestanddele in IBUPAIN FORTE (gelys in afdeling 6) hipersensitief (allergies) is.
• indien u vantevore 'n allergiese reaksie op aspirien of ander pyn/inflammasiemedikasie gehad het.
• indien u moeisame asemhaling soos gesien met emfiseem het, veral in die teenwoordigheid van blouverkleuring van die vel of lippe en oormatige slym, na 'n operasie van die galblaas of galweë, indien u aan akute alkoholisme of 'n konvulsiesteuring (of epilepsie) ly, indien u 'n hoofbesering gehad het of indien u met verhoogde druk binne u skedel gediagnoseer is, of indien u hartversaking sekondêr tot 'n chroniese longsiekte het (sien **Waarskuwings en voorsorgmaatreëls**).
• indien u medikasie genaamd monoamienoksidase-inhibeerders (MAOIs) vir die behandeling van depressie gebruik of indien u dit in die afgelope 14 dae gebruik het.
• indien u diarree vanweë inflammasie van u dermkanaal het wat moontlik die gevolg van die gebruik van antibiotika mag wees.
• indien u aan lewer- of nierinkorting ly.
• indien u tans 'n maagseer of bloeding vanaf die maag het of indien u 'n geskiedenis daarvan het. Dit kon vanweë die vorige gebruik van pyn-/inflammatoriese medikasie gewees het.
• indien u 'n hart- of bloedvatsiekte het.
• indien u ongekontroleerde asma of asemhalingsprobleme (benoude bors) het.
• indien u poliepe in u neus as gevolg van aspirien-geïnduseerde asma het.
• indien u bloedingsafwykings het.
• indien u hartversaking het.
• indien u jonger as 18 jaar is en vir pyn behandel word na die chirurgiese verwydering van u tonsils en/ of adenoïede, aangesien u 'n verhoogde risiko mag hê om ernstige en lewensbedreigende newe-effekte te ontwikkel.
• indien u 'n ultravinnige CYP2D6-metaboliseerder is. Dit is 'n lewerensiem wat medisyne afbreek (sien **Waarskuwings en voorsorgmaatreëls**).
• indien u swanger is vanweë die risiko vir nierdisfunksie in die fetus (sien **Swangerskap, borsvoeding en fertiliteit**).
• indien u borsvoed.
• indien u aan chroniese hardlywigheid ly.

Waarskuwings en voorsorgmaatreëls

IBUPAIN FORTE bevat parasetamol wat noodlottig in oordosis mag wees. In die geval van oordosering of vermoedelike oordosering en desnieteenstaande die feit dat die persoon asimptomaties mag wees, moet die naaste dokter, hospitaal of gifsentrum onmiddellik gekontak word.
IBUPAIN FORTE bevat kodeïen wat 'n opioïedmedisyne is. Herhaalde gebruik van IBUPAIN FORTE mag daartoe lei dat u daaraan gewoond raak (en hoër dosisse moet gebruik). Herhaalde gebruik van IBUPAIN mag ook tot afhanklikheid, misbruik en verslawing lei en dit mag 'n lewensdreigende oordosis tot gevolg hê.
Indien u IBUPAIN FORTE vir langer as die aanbevole tyd of in 'n hoër dosis as die aanbevole dosisse gebruik, loop u 'n risiko vir die ontwikkeling van ernstige nadelige effekte. Hierdie sluit ernstige skade aan die maag/dermkanaal en niere in sowel as vir baie lae bloedkaliumvlakke. Hierdie kan noodlottig wees (sien Moontlike newe-effekte).
Indien u enige van die volgende tekens ervaar terwyl u IBUPAIN FORTE neem, bespreek dit met u dokter of apteker aangesien dit daarop mag dui dat u afhanklik of verslaaf is:
• U moet hierdie medikasie langer gebruik as wat aanbeveel word
• U moet meer as die aanbevole dosis gebruik
• U gebruik hierdie medisyne vir redes wat nie medies van aard is nie, byvoorbeeld 'om kalm te bly' of om 'u te help slaap'
• U het herhaalde, onsuksesvolle pogings aangewend om daarmee op te hou of om die gebruik van hierdie medisyne te beheer
• Wanneer u ophou om hierdie medisyne te drink, voel u ongesteld en u voel weer beter wanneer u die medisyne neem ('onttrekkingseffekte').

Dosisse wat die aanbevole hoeveelhede oorskry mag erge lewerskade veroorsaak.

Die newe-effekte van IBUPAIN FORTE kan geminimaliseer word deur die laagste effektiewe dosis vir die kortste duur te neem.

IBUPAIN FORTE is vir korttermyn gebruik en word nie vir gebruik langer as 5 dae aanbeveel nie. Vanaf 20 weke swangerskapsduur en later mag IBUPAIN FORTE nierdisfunksie in die pasgeborene veroorsaak (sien **Swangerskap, borsvoeding en fertiliteit**).

Tref spesiale sorg met IBUPAIN FORTE:
IBUPAIN FORTE kan asma of allergiese reaksies tot gevolg hê. Indien u aan asma of 'n allergiese toestand ly, of 'n geskiedenis daarvan het, moet u die gebruik van IBUPAIN FORTE vermy.

U moet die gebruik van IBUPAIN FORTE in kombinasie met ander geneesmiddels wat vir die behandeling van inflammasie gebruik word (bekend as nie-steroïdale anti-inflammatoriese middels of NSAIMs), vermy. Voorbeelde sluit diklofenak en selekoksib in.

Indien u 'n geskiedenis van hoë bloeddruk het, sal u sorgvuldige monitering benodig terwyl u IBUPAIN FORTE neem. Dit mag vogretensie veroorsaak en dus tot hartversaking lei in pasiënte wie se hartfunksie gekompromitteerd is.

Die ibuprofeen in IBUPAIN FORTE is gekoppel aan 'n klein verhoogde risiko vir bloedklontvorming in die arteries wat 'n hartaanval of beroerte tot gevolg kan hê, veral indien dit in hoë dosisse (2400 mg/dag) gebruik word. Dit blyk asof laer dosisse (gelyk aan of minder as 1200 mg/dag) nie hierdie risiko inhou nie. Indien u vantevore 'n hartaanval of beroerte gehad het, gesels asseblief met u dokter voordat u IBUPAIN FORTE gebruik. U moet ook die gebruik daarvan met u dokter bespreek indien u ongekontroleerde hoë bloeddruk, hartvatsiekte (ook bekend as iskemiese hartsiekte) of slegte bloedsirkulasie vanweë verstopping van u arteries het.

Indien u ongekontroleerde hoë bloeddruk, hoë bloedlipied- of cholesterolvlakke, of suikersiekte (diabetes) het, of as u rook, mag u 'n verhoogde risiko vir ongunstige kardiale effekte hê, veral indien u IBUPAIN FORTE oor die langtermyn of in 'n hoë dosis gebruik.

Dermkanaalbloeding, -ulserasie of -perforasie, wat noodlottig kan wees, is met die gebruik van IBUPAIN FORTE tydens alle stadiums van behandeling gemeld. Dit het met of sonder waarskuwingsimptome of 'n vorige geskiedenis van ernstige newe-effekte van die dermkanaal voorgekom.

Die risiko vir newe-effekte van die dermkanaal is hoër met toenemende dosisse, in bejaardes, of indien u 'n geskiedenis van maagsere het.

U moet behandeling met IBUPAIN FORTE met die laagste moontlike dosering begin. Vra u dokter of apteker oor bykomende medikasie wat dermkanaalnewe-effekte kan voorkom indien u tot maagsere geneig is.

U moet u dokter kontak indien u enige newe-effekte van die buik oplet (veral bloeding wat met swart, teeragtige stoelgange kan voordoen). U moet die gebruik van IBUPAIN FORTE staak indien u bloeding oplet of vermoed dat u 'n maagseer het. Voordat u IBUPAIN FORTE gebruik, bekom advies by u dokter of apteker indien u met verswerende dikdermontsteking, Crohn se siekte, 'n mantelvliesbreuk, suurrefluks of abnormale bloedvatvorming gediagnoseer is.

NSAIMs, soos die ibuprofeen in IBUPAIN FORTE, mag nierversaking veroorsaak, veral in mense met ingekorte nierfunksie, ingekorte hartfunksie, abnormale lewerfunksie, en in diegene wat diuretika (waterpille) gebruik asook in bejaardes. Dit is nodig dat u dokter u nierfunksie onder hierdie omstandighede monitor. Bykomende sorg word vereis in gedehidreerde kinders en adolessente.

Hou op om IBUGESIC FORTE te neem met die eerste verskyning van 'n veluitslag, sere in die mond of enige ander teken van 'n allergiese reaksie. Ernstige velreaksies, wat noodlottig mag wees, is aangemeld (sien **Moontlike newe-effekte**). Indien u 'n koors of swelling van die limfkliere ontwikkel terwyl u IBUPAIN FORTE neem, staak gebruik en meld onmiddellik by u dokter aan.

IBUPAIN FORTE mag tekens van infeksie, soos koors en pyn, verbloem. Dit is dus moontlik dat IBUPAIN FORTE die toepaslike behandeling van infeksie mag vertraag en dit mag tot 'n verhoogde risiko vir komplikasies lei. Dit is met longontsteking veroorsaak deur bakterieë en met bakteriële velinfeksie wat op waterpokkies gevolg het, waargeneem. Indien u hierdie medisyne neem terwyl u 'n infeksie het en die simptome van u infeksie duur voort of vererger, moet u sonder versuim u dokter raadpleeg.

Bejaarde pasiënte het 'n verhoogde frekwensie van newe-effekte, veral maagsere en -bloeding, wat tot die dood mag lei. IBUPAIN FORTE kan ook asemhalingsprobleme in bejaardes veroorsaak. U moenie IBUBAIN FORTE met ander medisyne wat kodeïen bevat, kombineer nie.

Langtermyn en gereelde gebruik van pynmedikasie, en veral kombinasies van verskillende pynstillende middels, insluitende IBUPAIN FORTE, kan tot permanente nierskade en 'n risiko vir nierversaking aanleiding gee.

Langtermyn, ontoepaslike gebruik van hoë dosisse pynstillers, insluitende IBUPAIN FORTE, mag hoofpyne veroorsaak wat nie deur verhoogde dosisse van die medisyne behandel sal kan word nie.

Indien u galblaasprobleme of galstene het, moet u IBUPAIN FORTE met omsigtigheid gebruik, want dit kan spasma van die galweë veroorsaak wat weer tot buikpyn, wat kan kom en gaan, aanleiding mag gee.

U moet spesiale voorsorg tref indien u daartoe geneig is om medisyne te misbruik of indien u 'n dwelmprobleem het. U moenie IBUPAIN FORTE saam met ander kodeïenbevattende geneesmiddels gebruik nie. U mag toleransie (die behoefte om die dosis te vermeerder om dieselfde effek te verkry), fisiese en psigologiese afhanklikheid en ook opioïedgebruiksafwyking ontwikkel indien u herhaaldelik kodeïenbevattende medikasie gebruik. Misbruik of opsetlike oorgebruik van IBUPAIN FORTE kan tot oordosis en/of die dood lei (sien die vetgedrukte waarskuwing in die tabel hierbo).

Die gesamentlike gebruik van IBUPAIN FORTE en alkohol kan die risiko vir lewertoksisiteit verhoog.

Indien u 'n hoofbesering opdoen terwyl u IBUPAIN FORTE neem, lig asseblief u dokter of die personeel by die noodafdeling in dat u 'n kodeïenbevattende medisyne gebruik. IBUPAIN FORTE mag u risiko vir asemhalingsonderdrukking verhoog en so ook u risiko om verhoogde intrakraniale druk (binne die skedel) te ontwikkel. Dit mag ook sedasie veroorsaak asook veranderinge aan hoe u pupille op lig reageer en sodoende die kliniese verloop van u besering verbloem.

Indien u skildklier onderaktief is, het u 'n verhoogde risiko om asemhalingsprobleme en onderdrukking van die sentrale senuweesisteem (verlaagde harttempo en verlies van bewussyn vanweë geïnhibeerde breinaktiwiteit) met die gebruik van IBUPAIN FORTE te ondervind.

Indien u daarvan bewus is dat u lewerensieme (bekend as ensiem CYP2D6) medisyne baie vinnig metaboliseer, moet u nie IBUPAIN FORTE gebruik nie, aangesien dit baie gevaarlik kan wees. U mag simptome soos verwarring, slaperigheid, vlak asemhaling, klein pupille, naarheid, braking, hardlywigheid en aptytverlies en moeisame asemhaling ondervind vanweë die vinnige omskakeling van kodeïen na morfien in die liggaam.

U moenie IBUPAIN FORTE gebruik indien u swanger is of u baba borsvoed nie (sien **Moenie IBUPAIN FORTE gebruik nie** en **Swangerskap, borsvoeding en fertiliteit**). Die gebruik van IBUPAIN FORTE tydens swangerskap mag skadelik vir u baba wees.

Indien enige van die volgende op u van toepassing is, bespreek asseblief die gebruik van IBUPAIN FORTE met u dokter of apteker voordat u dit begin gebruik:
• u enige maagtoestand het omdat die diagnose verdoesel mag word.
• u 'n abnormale hartklop het (bekend as aritmie).
• u onlangs maagchirurgie gehad het.
• u bynierontoereikendheid ('n bynierafwyking) het.
• u prostaatprobleme of onlangs urienwegchirurgie gehad het.
• u 'n bloedtoestand bekend as anemie of bloedarmoede (met lae rooibloedseltellings) het, want dit kan dit erger maak.

Kinders en adolessente:
IBUPAIN FORTE moenie in kinders jonger as 12 jaar gebruik word nie.

Moenie IBUPAIN FORTE gebruik as jy jonger as 18 jaar is en behandeling vir pyn ontvang nadat jou mangels en/of adenoïede verwyder is nie, aangesien dit met 'n verhoogde risiko vir die ontwikkeling van ernstige en noodlottige newe-effekte geassosieer is.

Moenie IBUPAIN FORTE vir kinders gee wie se longfunksie gekompromitteer is nie (byvoorbeeld deur enige siekte wat hulle neuromuskulêre sisteem affekteer, erge hart- of longsiektes, boonste lugweg- of longinfeksies, veelvuldige trauma of uitgebreide chirurgiese prosedures).
Maak seker dat kinders en adolessente nie gedehidreer (ontwater) is wanneer hulle IBUPAIN FORTE neem nie, want dehidrasie mag die risiko vir nierinkorting verhoog.

Ander medisyne en IBUPAIN FORTE
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele geneesmiddels in).

Bespreek asseblief die gebruik van die volgende medisyne of substanse in kombinasie met IBUPAIN FORTE met u dokter of apteker voordat u dit begin gebruik:
• aspirien, kortikosteroïede (bv. prednisoon), metotreksaat, siklosporien, ander nie-steroïdale anti-inflammatoriese middels (bv. diklofenak, meloksikam, selekoksib, ens.)
• bloedverdunnende tablette (bv. warfarien) of antiplaatjiemedikasie (bv. lae-dosis aspirien, klopidogrel)
• antidepressante bekend as serotonienheropname-inhibeerders soos sitalopraam, paroksetien, fluoksetien
• alkohol
• bisfosfonate om osteoporose te behandel soos alendronaat of risedronaat
• pentoksifillien vir die behandeling van spierkrampe in mense met perifere arteriële siekte
• medikasie vir hoë bloeddruk bekend as AOE-inhibeerders (bv. perindopril, enalapril) of angiotensienreseptorblokkers (bv. losartaan, valsartaan) of "waterpille"
• hartmedikasie bekend as digoksien
• litium (vir gemoedsteurings)
• takrolimus (gebruik om orgaanverwerping na 'n oorplanting te voorkom)
• sidovudien (VIGS-medikasie)
• fenitoïen vir epilepsie
• antibiotika soos siprofloksasien, moksifloksasien, ens.
• mifepristoon (gebruik om 'n swangerskap te beëindig)
• sulfonielureums (soos gliklasied, glipisied, glimepiried) om suikersiekte te behandel
• probenesied vir die behandeling van jig
• cholesterolmedikasie bekend as cholestiramien
• medisyne vir die behandeling van naarheid en braking soos metoklopramied, domperidoon
• medisyne wat maaglediging vertraag soos ranitidien en sukralfaat
• antidepressante bekend as monoamienoksidase-inhibeerders (bv. moklobemied, selegilien, ens.) (sien **Moenie IBUPAIN FORTE gebruik nie**)
• sedeermiddels of slaapmedisyne soos bensodiasepiene (bv. alprasolaam), medisyne om angstigheid te behandel, antipsigotiese middels (bv. kwetiapien, risperidoon, olansapien), antihistamiene of trisikliese antidepressante (soos amitriptilien)
• simetidien (gebruik om maagsere en slegte spysvertering te behandel)
• loperamied en kaolien (medisyne om diarree te behandel)
• medisyne was as premedikasie voor operasies gebruik word of wat gebruik word om derm- of blaasprobleme te behandel, soos atropien, solifenasien, oksibutinien
• kinidien of meksiletien (gebruik om abnormale hartritmes te behandel)
• sisapried (gebruik om sooibrand te behandel)
• nalokson (gebruik om opioïedoordosis te behandel).

IBUPAIN FORTE kan die resultate van laboratoriumtoetse beïnvloed. Lig die persoon wat die toets doen in dat u IBUPAIN FORTE neem.

IBUPAIN FORTE met kos, drinkgoed en alkohol
U moenie alkohol drink terwyl u IBUPAIN FORTE gebruik nie. Dit is omdat alkohol die risiko vir ernstige newe-effekte kan verhoog.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of borsvoed, dink dat u swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u IBUPAIN FORTE gebruik.

U moenie IBUPAIN FORTE tydens swangerskap gebruik nie (sien **Moenie IBUPAIN FORTE neem nie**). Gedurende vroeë swangerskap mag ibuprofeen die inplanting van die bevrugte eier en die ontwikkeling van die embrio belemmer. Later in swangerskap kan dit die produksie van vrugwater verminder en tot abnormale nier- en longfunksie in die groeiende fetus aanleiding gee. Indien na aan voltyd gebruik word, kan dit die baba se bloedsirkulasie beïnvloed en vertraagde of verlengde kraam veroorsaak. Gesels asseblief met u dokter indien u meer inligting benodig.
IBUPAIN FORTE moenie tydens borsvoeding gebruik word nie (sien **Moenie IBUPAIN FORTE neem nie**).

Bestuur en die gebruik van masjinerie
IBUPAIN FORTE kan duiseligheid, lomerigheid, moegheid en visuele steurings veroorsaak. Dit mag ook u verstandelike skerpheid en vermoë om te konsentreer beïnvloed en dus ook u vermoë om veilig te bestuur. U moenie bestuur of masjinerie bedryf indien u hierdie effekte ervaar nie.
Dit is nie altyd moontlik om te voorspel tot watter mate IBUPAIN FORTE met u daaglikse aktiwiteite mag inmeng nie. Maak asseblief seker dat u nie die bogenoemde aktiwiteite beoefen voordat u nie bewus is van die mate waartoe IBUPAIN FORTE u beïnvloed nie.

3. Hoe om IBUPAIN FORTE te neem
Moenie u medisyne met enige ander persoon deel nie.
Neem IBUPAIN FORTE altyd presies soos wat dit in hierdie blaadjie beskryf word of soos wat u dokter gesê het. Raadpleeg u dokter of apteker indien u onseker is.

MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.
Newe-effekte kan tot 'n minimum beperk word deur die laagste effektiewe dosis vir die korste nodige duur om simptome te beheer, te gebruik. Indien u 'n infeksie het, raadpleeg u dokter sonder versuim indien u simptome (soos koors en pyn) voortduur of vererger (sien **Waarskuwing en voorsorgmaatreëls: Tref spesiale sorg met IBUPAIN FORTE**).

IBUPAIN FORTE is nie bedoel vir kinders jonger as 12-jarige ouderdom nie.

Volwassenes, bejaardes en kinders bo 12 jaar:
Neem een (1) tot twee (2) kapsules vier (4) tot ses (6) uurliks. Moenie meer as ses (6) kapsules in 24 uur gebruik nie.

U moenie IBUPAIN FORTE vir meer as 5 dae gebruik nie en indien u nie beter voel nie, moet u u dokter konsulteer.

Indien u lewer- of nierprobleme of Gilbert se sindroom (lewerafwyking) het, gesels met u dokter of apteker aangesien u 'n laer dosis sal moet neem en/of meer tyd tussen dosisse sal moet toelaat.

Bejaardes het 'n hoër risiko vir ernstige newe-effekte en moet derhalwe die laagste effektiewe dosis vir die korste moontlike duur gebruik. Indien u bejaard is, sal u gereeld vir dermkanaalbloeding (bv. van die maag of dermkanaal) gemoniteer moet word.

Indien u die indruk het dat die effek van IBUPAIN FORTE te sterk of te swak is, lig u dokter of apteker daaroor in.

Indien u meer IBUPAIN FORTE geneem het as wat u moes
Spoedige behandeling is essensieel.
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

'n Vertraging in die aanvang van behandeling vir parasetamoloordosering mag beteken dat behandeling te laat gegee word om effektief te wees. Oordosering met parasetamol kan tot lewerskade en die dood lei. Bejaardes, jong kinders, pasiënte met lewersiekte, alkoholiese pasiënte, wangevoede pasiënte of pasiënte wat ander medisyne met 'n effek op lewerensieme terselfdertyd geneem het, is veral vatbaar vir die skadelike gevolge van 'n oordosering

Simptome van parasetamoloordosering kom gewoonlik binne 24 uur voor en mag bleekheid, naarheid, braking, eetlusverlies en maagpyn insluit. Daarna mag u toestand verbeter; geringe maagpyn mag egter voortduur wat daarop mag dui dat u lewerskade het.

Oordosering met ibuprofeen mag die volgende simptome veroorsaak: naarheid, braking, maagpyn of, meer seldsaam, diarree. Tinnitus (suising in die ore), hoofpyn en dermkanaalbloeding (erge maagpyn, bloed in die stoelgang) is ook moontlik. Met meer ernstige vergiftiging, mag simptome duiseligheid, hoofpyn, lomerigheid, opwekking (gevoel van opwinding), disoriëntasie, koma en konvulsies insluit. Met ernstige vergiftiging mag die volgende voorkom: metaboliese asidose (hoë suurvlakke in die liggaam), verminderde bloedstolling, verergering van asma, nierversaking en lewerversaking.

Oordosering met kodeïen mag tot naarheid, braking, hipoksie (ontoereikende sirkulering van suurstof in die liggaam), hipotensie (lae bloeddruk wat u lighoofdig of duiselig mag laat voel), skok en hardlywigheid lei. U mag met 'n onderdrukte vlak van bewussyn, verkleining van u pupille se grootte en stadiger asemhaling voordoen.

U dokter sal die toepaslike behandeling vir u oordosis bepaal.

Indien u vergeet om IBUPAIN FORTE te neem
Moenie 'n dubbele dosis neem om vir vergete individuele dosisse te vergoed nie.

4. Moontlike newe-effekte
IBUPAIN FORTE kan newe-effekte hê.

Nie alle newe-effekte wat vir IBUPAIN FORTE gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige effekte ervaar terwyl u IBUPAIN FORTE neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou om op IBUPAIN FORTE te neem en lig u dokter onmiddellik in of gaan na die ongevalle-afdeling van u naaste hospitaal:
• swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat moeisame sluk of asemhaling mag veroorsaak.
• uitslag of jeuk.
• floutes.
• geel verkleuring van die vel of oë, ook bekend as geelsug.
• tekens van intestinale bloeding soos: helderrooi stoelgang, swart teeragtige stoelgange (melena), braking van bloed (hematemese) of donker partikels wat soos koffiemoer lyk.
• ernstige velreaksies wat die volgende mag insluit: rooiheid, galbulte (rooi, jeukende knoppe), blase, pustules, afskilfering van die vel en bloeding in die lippe, oë, mond, neus en genitalieë (toksiese epidermale nekrolise, Stevens-Johnsonsindroom of veelvuldige eriteem).
• 'n ernstige velreaksie bekend as DRESS-sindroom waarvan die simptome veluitslag, koors en swelling van die limfnodes mag insluit.
• 'n rooi, afskilferende, wydverspreide uitslag met knoppe onder die vel en blase wat hoofsaaklik op velvoue, die romp en boonste ledemate gelokaliseer is vergesel van koors, met die aanvang van behandeling (akute, verspreide eksantemiese pustulose).
• vel wat sensitief vir lig word.
• spierswakheid of lighoofdigheid. IBUPAIN FORTE kan, veral as dit in hoër as die aanbevole dosisse of vir verlengde periodes geneem word, nierskade veroorsaak en verhoed dat die niere sure behoorlik vanuit u bloed na die urien verwyder (renale tubulêre asidose). Dit kan ook baie lae bloedkaliumvlakke veroorsaak (sien **Waarskuwings en voorsorgmaatreëls**). Dit is 'n baie ernstige toestand wat onmiddellike behandeling verg. Tekens en simptome sluit spierswakheid en lighoofdigheid in (soos gemeld).
• pankreatitis (inflammasie van die pankreas) wat mag voordoen met erge pyn in die boonste gedeelte van buik wat na die rug kan versprei, 'n geswelde en teer buik en koors.
• stuipe.
• meningitis of verhoogde druk binne die skedel wat 'n stywe nek, hoofpyn, naarheid, braking, koors en disoriëntasie mag veroorsaak.
• enige veranderinge in visie, insluitende dowwe of dubbelvisie, omdat dit op inflammasie van u oogsenuwee mag dui.
• hartversaking wat kan voordoen met swelling van die hande en voete of erge kortasemheid.
• asma, fluitende asemhaling of kortasemheid, of moeisame asemhaling.

Hierdie is almal baie ernstige newe-effekte. Indien u <u>enige daarvan</u> het, mag u 'n baie ernstige reaksie op IBUPAIN FORTE gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Lig u dokter in indien u enige van die volgende oplet:
Die volgende newe-effekte is dikwels ervaar:
• maagsere
• slegte spysvertering
• naarheid
• braking
• diarree (loopmaag)
• maagkrampe of -pyn
• buikopsetting
• winderigheid
• hardlywigheid
• sere in die mond
• verergering van derminflammasie en Crohn se siekte
• ontsteking van die maag (gastritis)
• lomerigheid
• duiseligheid
• stuipe
• verslawing (sien **Waarskuwings en voorsorgmaatreëls**)
• toleransie (sien **Waarskuwings en voorsorgmaatreëls**)
• afhanklikheid (sien **Waarskuwings en voorsorgmaatreëls**)
• hoofpyn
• vertigo (versteuring van balans)
• malaise (algemene gevoel van ongemak)
• slaapsteurings.

Die volgende newe-effekte is minder dikwels ervaar:
• loopneus
• bloedafwykings (vermindering in witbloedselle wat u risiko vir infeksie mag verhoog en verminderde plaatjies wat tot maklike kneusing of bloeding mag lei)
• bloedarmoede vanweë verlagings in rooibloedseltellings wat tot bleekheid, moegheid en kortasemheid mag lei
• slaaploosheid
• angstigheid
• depressie
• staat van verwarring
• hallusinasies
• gevoel van depressie of hartseer of intense vreugde vir geen spesifieke rede nie
• gemoedsveranderinge
• rusteloosheid
• senuweeagtigheid
• spelde-en-naalde in hande en voete
• moeg voel
• verkleining van die pupil
• inkorting van gehoor
• hoor geluide wanneer geen eksterne geluide teenwoordig is nie
• veranderinge in hartklop
• hoë bloeddruk
• duiseligheid wanneer daar regop gekom word
• koud voel
• blosing van die gesig
• droë mond
• inkorting van nier- en lewerfunksie
• galwegspasma (wat pyn aan die regter kant van u buik mag veroorsaak, veral na 'n maaltyd; die pyn kan na die regter skouer versprei)
• pyn en moeite om urien te passeer of 'n verlaagde behoefte om so te doen
• spasma van die urienweë
• uitputting.

Die frekwensie van die volgende newe-effekte is nie bekend nie:
• vermeerderde sweet
• irriteerbaarheid
• nagmerries
• onbeheerbare spierbewegings
• onderdrukking van hoes
• eetlusverlies
• spierstyfheid
• verlaagde libido of potensie
• hipotermie.

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte kry, gesels met u dokter, apteker of verpleegsuster. U kan newe-effekte ook aan die SARGP via die Med Safety TOEP (Medsafety X SAHPRA) of deur die elektroniese aanmelding (who-umc.org) op die SAHPRA webwerf rapporteer. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van IBUPAIN FORTE te voorsien. Vermoedelike newe-effekte kan ook direk aan die houer van die registrasiesertifikaat (HCR) by customercare@kiarahealth.com aangemeld word.

5. Hoe om IBUPAIN FORTE te berg
Bewaar op 'n droë plek teen of onder 25 °C. Beskerm teen lig.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Besorg alle ongebruikte medisyne aan u apteker terug.
Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.
Moenie na die vervaldatum wat op die bottel en karton aangedui is, gebruik nie.

6. Inhoud van die pakkie en ander inligting
Wat IBUPAIN FORTE-kapsules bevat
Die aktiewe bestanddele is ibuprofeen 200 mg, kodeïenfosfaat 10 mg en parasetamol 250 mg.
Die ander bestanddele in die kapsule is vooraf-gegelatineerde stysel, mikrokristallyne sellulose, gesuiwerde talk.
Die kapsuledop bestaan uit eritrosien, rooi ysteroksied, titaandioksied, geel ysteroksied, gelatien, indigo karmyn, kinoloongeel.

Waarna IBUPAIN FORTE lyk en inhoud van die verpakking
IBUPAIN FORTE is grootte 0 kapsules met 'n rooi romp en donkergroen doppie wat 'n vryvloeiende wit poeier bevat.

IBUPAIN FORTE word verpak in:
Wit ondeursigtige sekuriteitshouers met aanklip, laedigtheid, mediumdigtheid of hoëdigtheid poliëtileen peuterbestande seëls met 10, 30, 60, 100 of 500 kapsules.
Helder PVC- of Tristar-stulpstroke geseël met aluminiumfoelie met 10, 30, 60, 100 of 500 kapsules verpak binne-in 'n kartondoos.
Geseëlde aluminium, plat, gereed-vir-die-pasiënt-sakkies met LDPE-geribbelde ritssluiters met 30, 60 of 100 kapsules.
Amberkleurige glashouers met swart, harde, plastiese (polipropileen) skroefdoppe met uitgebreide LDPC-binneste seëls met 30, 60 of 100 kapsules.
Nie alle verpakkingsgroottes mag bemark word nie.

Houer van die Sertifikaat van Registrasie
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Toegang tot die ooreenstemmende Professionele Inligting
Om toegange tot die professionele inligting te verkry, stuur 'n e-pos aan customercare@kiarahealth.com

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