PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

Ibupain® Forte (capsules)

Ibuprofen, Paracetamol and Codeine phosphate.

Sugar free.

Read all of this leaflet carefully before you start taking IBUPAIN FORTE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- IBUPAIN FORTE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

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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.
- 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.
- if you suffer from severe liver impairment.
- if you have, or have a history of, a bleeding stomach ulcer. This can be due to previous use of pain/inflammation medication you have taken.
- if you have uncontrolled asthma or breathing difficulties.
- if you have nasal polyps due to aspirin-induced asthma.
- if you have bleeding disorders.
- if have suffer from heart failure.
- if you have severe kidney failure.
- if you are a child (0 - 18 years of age) who is being treated for pain after surgery to remove the tonsils and or adenoids, as there is an increased risk of developing serious and fatal side effects.
- if you are an ultra-rapid CYP2D6 metaboliser. This is a liver enzyme that metabolises medicines.
- if you are pregnant, due to risk of kidney dysfunction in the foetus.
- if you are breastfeeding.
- if you suffer from chronic constipation.

Warnings and precautions

This product 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.

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 neonates.

Take special care with IBUPAIN FORTE:

If you are suffering from or have a history of asthma or allergic diseases, this can be triggered by IBUPAIN FORTE. The use of IBUPAIN FORTE should be avoided if this is the case.

Your conditions should be appropriately monitored if you have high blood pressure or any type of heart disease while taking IBUPAIN FORTE. Your risk of heart disease is increased if you are smoking, have diabetes (increased sugar levels in your blood), high cholesterol or high blood pressure. IBUPAIN FORTE can result in heart failure in some compromised patients.

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 in the elderly, or if you have a history of stomach ulcers.

You need to start your dosing of IBUPAIN FORTE on the lowest possible dose and additional medication that can prevent gastrointestinal side effects should be considered if you are prone to stomach ulcers.

You should contact your doctor if you notice any abdominal side effects (especially bleeding). You should stop taking IBUPAIN FORTE if you notice bleeding or suspect that you have a stomach ulcer.

IBUPAIN FORTE should be stopped at the first appearance of skin rash, sores in your mouth, or any other sign of allergic reaction. Serious skin reactions, which can be fatal, have been reported.

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 in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine 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.

Kidney or liver damage can occur with frequent use of IBUPAIN FORTE in the elderly and patients taking diuretics (water tablets to treat high blood pressure). If you are at risk of these side effects, your doctor may monitor your kidney function.

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, IBUPAIN FORTE, may cause a spasm of the biliary tract, which will result in abdominal pain, which comes and goes.

You should take special care if you have the tendency to misuse medicine or have a drug problem. You can become dependent on IBUPAIN FORTE if you are taking high doses for extended periods.

You should not take IBUPAIN FORTE with other codeine containing medicines.

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

Take care if you have had head injury as IBUPAIN FORTE can obscure the symptoms thereof and result in increased brain swelling.

If your thyroid gland is underproductive, 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).

If you know that you are a fast metaboliser of the liver enzyme CYP2D6, 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, difficulty breathing.

Using IBUPAIN FORTE if you are in your third trimester (month 6 – 9) of pregnancy can have serious effects on your foetus. This can result in the delayed onset and increased duration of the labour process. It could also result in pulmonary hypertension (high blood pressure in the lungs) of the new-born.

You should take caution if

- you have any stomach condition as the diagnosis may be obscured.
- you have a history of gastrointestinal disease (e.g. ulcerative colitis (inflammation of the intestines), Crohn's disease (inflammation of the gastrointestinal tract), hiatus hernia (when the upper part of the stomach pushes through the diaphragm), gastro-oesophageal reflux disease (heartburn), angiodysplasia (a malformation of a vein in the stomach)) as the condition may be exacerbated.
- you have a heart beat (arrhythmia) irregularity.
- you have had recent stomach surgery.
- you have liver or kidney impairment.
- you have adrenocortical insufficiency (adrenal gland disorder).
- you have prostate problems or have recently had urinary tract surgery.
- you have an infection as it can worsen and mask the symptoms.
- you have a blood condition called anaemia, 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 a child (0 - 18 years of age) who is being treated for pain after surgery to remove the tonsils and/or adenoids, as there is an increased risk of developing serious and fatal side effects.

IBUPAIN FORTE should not be given to children who have any respiratory deficiency (any disease that affect their neuromuscular system, severe heart of breathing disorders, lung infections, multiple 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).

The following medicines should not be taken together with IBUPAIN FORTE:

- aspirin, corticosteroids (e.g. prednisone), methotrexate, ciclosporin, other non-steroidal anti-inflammatory medicines (e.g. diclofenac, meloxicam, etc.)
- blood thinning tablets (e.g. warfarin)
- antidepressant medicines such as citalopram, paroxetine, fluoxetine
- medicines to treat high blood pressure, or “water tablets”
- heart medication
- lithium (for mood disorders)
- tacrolimus (used during organ transplants)
- zidovudine (AIDS medication)
- antibiotics like ciprofloxacin, moxifloxacin etc.
- mifepristone (used to end a pregnancy)
- probenecid used in the treatment of gout
- cholesterol medication called cholestyramine
- antidiarrheal medicine metoclopramide, domperidone
- antidepressants called monoamine oxidase inhibitors (e.g. moclobemide, selegiline, etc.)
- sedative medicine, antipsychotics, antihistamines

- alcohol
- cimetidine (used to treat stomach ulcers and indigestion)
- loperamide and kaolin (medicines to treat diarrhoea)
- medicines which are used as premedication before operations and after heart attacks such as atropine
- 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”).

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. You should not drive or operate machinery if you experience these effects.

3. How to take IBUPAIN FORTE

Do not share medicines prescribed for you 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 “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:

1 to 2 capsules 6 hourly. Do not take more than 8 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.

In patients with 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 and for the shortest possible duration. Elderly patients should also 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 light headed 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).

These are all very serious side effects. If you have 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
- perforation or gastrointestinal bleeding, sometimes fatal
- indigestion
- nausea
- vomiting
- diarrhoea
- abdominal cramps and pain
- bloating
- flatulence
- constipation
- mouth ulcers
- exacerbation of bowel inflammation and Crohn’s disease
- gastritis

- pancreatitis (inflammation of the pancreas) which may present as pain in the upper part of the stomach, going into your back, a swollen and tender belly, fever
- drowsiness
- dizziness
- seizures
- addiction
- tolerance
- dependence
- headache
- vertigo (balance disturbances)
- malaise (general feeling of uneasiness)
- sleep disturbances

The following side effects were experienced less frequently:

- runny nose and meningitis (stiff neck, headache, nausea, vomiting, fever or disorientation)
- blood disorders (lowered white blood cells that increases your risk of infections, decreased platelets and neutrophils)
- decrease in haemoglobin (seen in blood tests)
- 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
- inflammation of the optic nerve (in your eye)
- feeling tired
- visual disturbances
- narrowing of the pupil
- hearing impairment
- hearing sound when no external sound is present
- changes to your heart beat
- heart failure
- swelling of hands and feet
- high blood pressure
- dizziness when getting in the upright position
- feeling cold
- facial flushing
- asthma
- wheezing or shortness of breath
- difficulty breathing
- dry mouth
- impairment of renal and liver function
- yellowing of eyes and skin
- increased liver enzymes
- 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
- skin rash
- sensitivity of the skin to sunlight
- fatigue.

The frequency of the following side effects are unknown:

- increased sweating
- irritability
- nightmares
- increased pressure within your head (raised intracranial pressure)
- uncontrolled muscle movements
- blurred or double vision
- suppression of cough
- dull pain in the middle to upper right area of the abdomen (biliary colic)
- decreased appetite
- muscle stiffness.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. 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 Patientsafety.sacg@novartis.com.

5. How to store IBUPAIN FORTE

Keep in a dry place 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, paracetamol and codeine phosphate.

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 securitainers 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.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Magwa Crescent West

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Jukskei View

2090

This leaflet was last revised in

25 August 2021

Registration number

37/2.8/0060

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07