1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

IBUMOL 350 mg/200 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of IBUMOL contains 350 mg of paracetamol and 200 mg of ibuprofen.

Sugar free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

IBUMOL is a round, white, biconvex tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

IBUMOL is used for the short term management of mild to moderate pain of inflammatory origin in adults and children over 12 years of age for a maximum treatment period of 10 days.

4.2. Posology and method of administration

Posology:

Adults: One to two tablets three times a day, if necessary.

Maximum of 6 tablets per day.

To be taken preferably with or after food.

DO NOT EXCEED THE RECOMMENDED DOSE.

Use the lowest effective dose for the shortest possible duration of treatment.

Do not take IBUMOL for longer than 10 days.

Special populations:

Paediatric population:

Not recommended for children under 12 years of age.

Method of administration:

For oral administration.

4.3. Contraindications

IBUMOL is contraindicated in:

- Hypersensitivity to paracetamol, ibuprofen or any excipients in IBUMOL (see section 6.1).
- History of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous use of IBUMOL or other NSAIDs.
- Active or history of recurrent gastrointestinal ulcer or haemorrhage or perforations.
- Heart failure, severe hepatic impairment or hepatic failure and severe renal impairment.
- IBUMOL should not be used in patients sensitive to aspirin or another non-steroidal

anti-inflammatory medicines.

- Because of the possibility of cross-sensitivity due to structural relationships which exists among non-steroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.
- Uncontrolled asthma or bronchospasm.
- Nasal polyps associated with aspirin-induced bronchospasm.
- IBUMOL is contraindicated during the last trimester of pregnancy (see sections 4.4 and 4.6).
- Severe liver impairment.

4.4. Special warnings and precautions for use

Paracetamol

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

Do not use continuously for more than 10 days without consulting your doctor.

If pain persists for longer than 10 days, or if taking for fever and the fever persists for longer than 3 days or if the condition deteriorates or new symptoms develop, a doctor should be contacted as additional treatment may be necessary.

Renal or hepatic impairment

IBUMOL should be given with care to patients with impaired kidney or liver function. The

larger dose should be avoided in patients with hepatic impairment.

Alcohol effects

Avoid alcohol. Increased risk of liver toxicity, especially in alcoholics with high doses and prolonged use. It should also be given with care to patients with alcohol dependence.

High Anion gap metabolic acidosis (HAGMA)

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors. Use with caution in patients with glutathione depletion due to metabolic deficiencies (see section 4.5).

Severe cutaneous adverse reactions (SCARs)

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

Ibuprofen

Cardiovascular and cerebrovascular effects

Cases of Kounis syndrome have been reported in patients treated with IBUMOL. Kounis syndrome is defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

Caution is required with IBUMOL in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with IBUMOL therapy (see section 4.3).
The use of ibuprofen, as contained in IBUMOL, 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).

Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen 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.

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in compromised patients.

Elderly

The elderly have an increased frequency of adverse reactions to NSAIDs, such as IBUMOL, especially gastrointestinal perforation, ulceration or bleeding (PUBs) which may be fatal.

Gastrointestinal

The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of IBUMOL, in patients with a history of ulcers, and the elderly. These patients are more likely to develop adverse hepatic or renal effects.
When gastrointestinal perforation, ulceration or bleeding (PUBs) occurs in patients receiving IBUMOL, treatment with IBUMOL should be stopped.

IBUMOL should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Skin reactions

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. IBUMOL should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Drug reactions with Eosinophilia and systemic symptoms (DRESS) has been reported in patients taking NSAIDs such as IBUMOL. 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 manifestation of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue IBUMOL and evaluate the patient immediately.

Foetal Toxicity

Regular use of NSAIDs such as IBUMOL 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.

Limit use of NSAIDs, including IBUMOL, between 20 to 30 weeks of pregnancy due to the risk of oligohydramnios/foetal renal dysfunction. Avoid use of NSAIDs in women around 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/foetal renal dysfunction and premature closure of the foetal ductus arteriosus.

If NSAID treatment is necessary between 20 weeks and 30 weeks gestation, limit IBUMOL use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if IBUMOL treatment extends beyond 48 hours. Discontinue IBUMOL if oligohydramnios occurs and follow up according to clinical practice.

Impaired female fertility

The use of IBUMOL 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 IBUMOL should be considered (see section 4.6).

Hepatic effects

Hepatic function impairment which may increase risk of hepatotoxicity.

Renal effects

Renal function impairment where renal failure may be provoked, especially in patients with pre-existing renal impairment.

There is a risk of renal impairment in dehydrated children and adolescents.
Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

Asthma may be exacerbated.

Masking of symptoms and infections

The antipyretic, analgesic and anti-inflammatory action of IBUMOL may mask symptoms of the occurrence of worsening of infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. Therefore, when ibuprofen as contained in IBUMOL is administered for pain or fever in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

Haematological effects

IBUMOL can interfere with platelet aggregation and has been shown to prolong bleeding time in normal subjects.

Anaemia may be exacerbated.

SLE and mixed connective tissue disease

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis (see section 4.8).

4.5. Interaction with other medicines and other forms of interaction

Care should be taken in patients treated with any of the following medicines as interactions have been reported in some patients.

Paracetamol

Enzyme inducing and hepatotoxic medicine: Increased risk of hepatoxicity. Possible decrease in therapeutic effects of paracetamol.

Metoclopramide and domperidone: Absorption of paracetamol may be accelerated.

Warfarin and other coumarins: anticoagulant effect may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding.

Cholestyramine: Absorption of paracetamol is reduced if given within one hour of cholestyramine.

Probenecid: Excretion of paracetamol may be affected and plasma concentrations altered.

Flucloxacillin: caution should be taken when paracetamol is used concomitantly with

flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4).

Ibuprofen:

NSAIDs: Use of two or more NSAIDs concomitantly could result in an increase in side effects.

Corticosteroids: Increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs).

Anticoagulants: IBUMOL may enhance the effects of anticoagulants such as warfarin.

Antiplatelet medicines (e.g. aspirin, clopidogrel and ticlopidine) *and selective serotonin reuptake inhibitors (SSRIs):* Increased risk of gastrointestinal bleeding and ulceration.

Antihypertensives, beta-blockers and diuretics: NSAIDs may reduce the effect of antihypertensives, such as ACE inhibitors, beta-blockers and diuretics. There may be an increased risk of hyperkalaemia.

Aminoglycosides: NSAIDs may decrease the excretion of aminoglycosides.

Antidiabetic medicines (e.g. sulfonylureas): Hypoglycaemic effects of these medicines may be increased.

Digoxin: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma digoxin levels. Frequent monitoring of digoxin levels is advised.

Ciclosporin and tacrolimus: Increased risk of nephrotoxicity.

Lithium: Increase in the steady-state concentration of lithium. Frequent monitoring of lithium levels is advised.

Methotrexate: Increased and prolonged methotrexate plasma concentration and an increased risk of methotrexate toxicity.

Diuretics: Can also increase the risk of nephrotoxicity of NSAIDs.

Mifepristone: IBUMOL should not be used 8 to 12 days after mifepristone as IBUMOL can reduce the effect of mifepristone.

Quinolone antibiotics: Patients taking IBUMOL and quinolones may have an increased risk of developing convulsions.

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

Bone marrow depressants: The leucopenic and/or thrombocytopenic effects of theses medicines may be increased.

The risk of gastrointestinal bleeding and ulceration is increased when used with alcohol, biphosphonates or oxypentifylline.

4.6. Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and lactation has not been established (see section 4.3).

Pregnancy

Ibuprofen:

First trimester:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies raise concern about 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 increased from less than 1 %, up to approximately 1,5 %. 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.

Second and third trimesters:

During the third trimester of pregnancy, prostaglandin synthesis inhibitors, may expose the foetus to:

cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension); renal dysfunction, which may progress to renal failure with oligo hydroamniosis.

At the end of pregnancy, the mother and the neonate may be exposed to: possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses; inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, IBUMOL is contraindicated during the third trimester of pregnancy. IBUMOL should be used with caution in the first and second trimesters of pregnancy.

Lactation

Ibuprofen:

IBUMOL should be avoided when breastfeeding.

Fertility

Ibuprofen:

There are reports of that NSAIDs medicines may cause reversible impairment of female fertility by an effect of ovulation (see section 4.4).

4.7. Effects on ability to drive and use machines

Effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking IBUMOL. If affected, patients should not drive or operate machinery.

4.8. Undesirable effects

a) Summary of the safety profile

Ibuprofen

The most commonly adverse events observed with the use of ibuprofen as contained in IBUMOL are gastrointestinal in nature, such as for example, nausea, abdominal cramps and pain. Dizziness, skin rash, pruritus are also the most frequently occurring adverse reactions after taking ibuprofen as contained in IBUMOL.

b) Tabulated list of adverse reactions

Paracetamol

System organ class	Frequent	Less frequent	Frequency unknown (cannot be estimated from the available data)
Blood and the lymphatic system disorders		Haematological reactions (including agranulocytosis, thrombocytopenia, neutropenia, pancytopenia, leukopenia)	
Immune system disorders		Anaphylaxis, cutaneous hypersensitivity reactions (skin rashes and angioedema), serious skin reactions	
Metabolism and nutrition disorders			High anion gap metabolic acidosis
Respiratory, thoracic and mediastinal disorders		Bronchospasm (more likely in asthmatics sensitive to NSAIDs)	
Hepatobiliary disorders		Hepatitis, hepatic dysfunction	Pancreatitis
Skin and subcutaneous tissue disorders			Sensitivity reactions resulting in reversible skin rash (which may be accompanied by fever and mucosal lesions)
Renal and urinary disorders			Renal failure, renal colic

Post-marketing experience:

System organ class	Frequent	Less frequent	Frequency unknown (cannot be estimated from the available data)
Skin and subcutaneous tissue disorders			Severe cutaneous drug reactions (SCARs) including DRESS reaction, fixed drug eruptions (FDE) and drug-induced

			hypersensitivity syndrome (DIHS).

Ibuprofen

System organ class	Frequent	Less frequent	Frequency unknown (cannot be estimated from the available data)
Infections and infestations		Rhinitis, 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	
Blood and the lymphatic system disorders		Neutropenia, thrombocytopenia with or without purpura, agranulocytosis, anaemias (aplastic anaemia and haemolytic anaemia)	Eosinophilia
Immune system disorders		Hypersensitivity reactions, (a) non-specific allergic reaction such anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm, dyspnoea or alveolitis, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely, exfoliative and bullous dermatoses	

Psychiatric disorders		Nervousness, insomnia	Confusion, anxiety, depression, hallucination
Nervous system disorders	Dizziness	Drowsiness, headache	Paraesthesia, somnolence
Eye disorders		Blurred vision and other ocular reactions	Visual impairment, optic neuritis
Ear and labyrinth disorders		Tinnitus	Hearing impaired, vertigo
Cardiac disorders		Hypertension	Oedema, cardiac failure
Vascular disorders			Hypertension, Kounis syndrome
Gastrointestinal disorders	Nausea, abdominal cramps and pain	Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, bloating, constipation, decreased appetite, diarrhoea, melaena, haematemesis, pancreatitis	Gastrointestinal perforation, dyspepsia, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis
Hepatobiliary disorders		Hepatitis and jaundice	Abnormalities of liver function test, hepatic failure
Skin and subcutaneous tissue disorders	Skin rash, pruritus	Bullous reactions, Severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, exfoliative dermatitis)	Photosensitivity reaction, Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), Acute generalised exanthematous pustulosis (AGEP)
Renal and urinary disorders		Impaired renal functions, acute reversible renal failure, toxic nephropathy in various forms, including interstitial nephritis, nephrotic syndrome, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema	Renal insufficiency, ureteric colic, dysuria

Investigations		Decreased haemoglobin levels	

Post-marketing experience

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Metabolism and Nutrition Disorders			Hypokalaemia
Renal and Urinary Disorders			Renal tubular acidosis

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. Healthcare 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.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

4.9. Overdose

Paracetamol

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly. 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.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 g/day to 10 g/day) of paracetamol for several days, 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.

Symptoms of paracetamol overdose: In the first 24 hours include pallor, nausea, vomiting, anorexia and possibly 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 dysrhythmias have been reported.

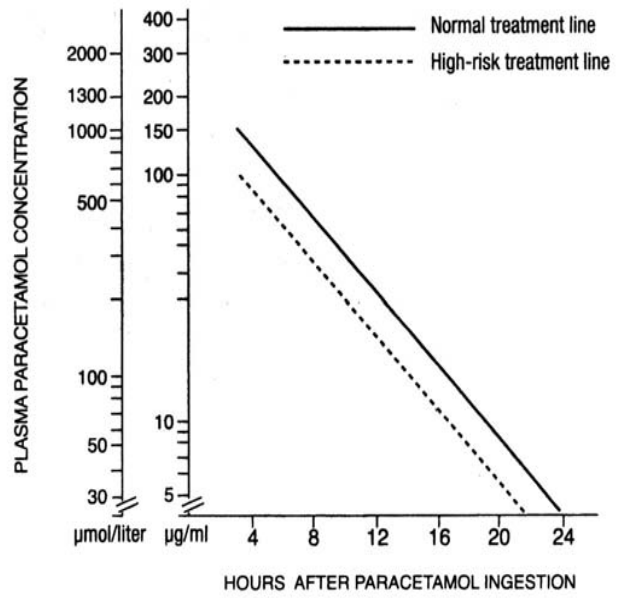
Treatment for paracetamol overdose:

Although evidence is limited it is recommended that an adult who has ingested 5 g to 10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above).

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight 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 four hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen 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 four hours for seventeen doses.

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



Those whose plasma paracetamol levels are above the “Normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen 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 ninety-six hours.

Ibuprofen

Symptoms of ibuprofen overdose

Most patients who have ingested significant amounts of ibuprofen will manifest symptoms within 4 to 6 hours.

The most frequently reported symptoms of overdose include nausea, vomiting, abdominal pain, lethargy and drowsiness. Central nervous system (CNS) effects include headache, tinnitus, dizziness, convulsion, and loss of consciousness. Nystagmus, metabolic acidosis,

hypothermia, renal effects, gastrointestinal bleeding, coma, apnoea, diarrhoea and depression of the CNS and respiratory system have also been rarely reported. Disorientation, excitation, fainting and cardiovascular toxicity, including hypotension, bradycardia and tachycardia have been reported. In cases of significant overdose, renal failure and liver damage are possible.

Therapeutic measures

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A 2.8 Analgesic combinations

ATC Code: M01AE51 – Musculoskeletal system, anti-inflammatory and antirheumatic products, non-steroids, propionic acid derivatives. Ibuprofen combinations.

Mechanism of action

Ibuprofen has analgesic, antipyretic and anti-inflammatory activities.

Ibuprofen exerts its anti-inflammatory action peripherally in inflamed tissue by reducing prostaglandin activity and by inhibiting synthesis and/or actions of other local mediators of the inflammatory response.

Paracetamol has analgesic and antipyretic effects.

5.2. Pharmacokinetic properties

Paracetamol:

Absorption following oral administration is almost complete. 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. Paracetamol is renally excreted primarily as metabolites and 3 % of a dose may be excreted unchanged.

Ibuprofen:

Well absorbed after oral administration. The half-life of ibuprofen is about 2 hours. More than 90 % of an ingested dose is excreted in the urine as metabolites or their conjugates.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch, purified talc.

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 °C in a well-closed container.

Protect from light and moisture.

Keep in original packaging until required for use.

6.5. Nature and contents of container

18 or 30 tablets are packed in a white, polypropylene container with a white, round, low density polyethylene lid together with a white, silica gel sachet, together with a leaflet.

20 tablets are packed in a white, polypropylene container with a white, polyethylene push-on cap together with a white, silica gel sachet, together with a leaflet.

Not all pack sizes are necessarily marketed.

6.6. Special precautions for disposal

No special requirements

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Tel: 0800 118 088

8. REGISTRATION NUMBER

34/2.8/0089

9. DATE OF FIRST AUTHORISATION

06 June 2003

10. DATE OF REVISION OF TEXT

05 October 2026

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

Botswana: B9309080 S3

Namibia: NS1 04/2.8/2014