1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF MEDICINE

IBUMOL BANANA 250/200 mg per 10 ml suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml suspension of IBUMOL BANANA contains 250 mg of paracetamol and 200 mg of ibuprofen.

Contains preservative:

Sodium benzoate 0,1 % *m/v*

Contains sugar: Sorbitol 4 g and glycerol 630,5 mg

Contains sweetener: Sodium cyclamate 50 mg, saccharin sodium 7 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.

IBUMOL BANANA is a homogenous, yellow suspension with a sweet, fruity, banana odour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

IBUMOL BANANA is indicated for the treatment of mild to moderate pain of inflammatory origin or non-inflammatory origin with or without fever.

4.2. Posology and method of administration

Posology:

DO NOT EXCEED THE RECOMMENDED DOSE.

SHAKE BOTTLE BEFORE USE.

Adults and children over twelve years:

Take one to two medicine measurefuls (5 ml to 10 ml) four hourly if necessary and not more than six medicine measurefuls in twenty-four hours.

Special populations:

Paediatric population:

Children six to twelve years old:

Take one to two medicine measurefuls (5 ml to 10 ml) three to four times daily.

Children two to five years old:

Take half to one medicine measurefuls (2,5 ml to 5 ml) three to four times daily.

Safety in children under two years of age has not been proven.

IBUMOL BANANA should be taken with or after food.

If taking IBUMOL BANANA for pain and the pain persists for longer than 7 days, or if taking IBUMOL BANANA for fever and the fever persists for longer than 3 days, or if the condition deteriorates or new symptoms develop, a re-evaluation of the condition is required by the doctor.

Method of administration:

For oral administration.

4.3. Contraindications

Allergy to paracetamol, ibuprofen or any of the other ingredients of IBUMOL BANANA (see section 6.1)

Paracetamol:

Severe liver impairment.

Ibuprofen:

- Peptic ulcer disease or gastrointestinal bleeding.
- Patients sensitive to aspirin or another nonsteroidal anti-inflammatory medicines.
- Uncontrolled asthma or bronchospasm.
- Nasal polyps associated with aspirin-induced bronchospasm.
- Patients with bleeding disorders.
- Cardiovascular diseases.
- Renal impairment.
- Last trimester of pregnancy and lactation (see section 4.6).
- Patients who are receiving coumarin-anticoagulants.

4.4. Special warnings and precautions for use

IBUMOL BANANA 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.

Paracetamol

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

Severe cutaneous adverse reactions (SCARs)

SCARs such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients with paracetamol containing medicines. If a patient develops SCARs, treatment with IBUMOL BANANA must immediately be discontinued and appropriate treatment instituted.

High anion gap metabolic acidosis (HAGMA)

Cases of 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).

Hepatic impairment

Use with caution in alcoholism or impaired liver function - Increased risk of hepatotoxicity.

Alcohol

Avoid alcohol, especially in alcoholics with high doses and prolonged use.

Ibuprofen

Cardiovascular and cerebrovascular effects

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

Conditions predisposing to and exacerbated by fluid retention such as compromised cardiac function, congestive heart disease, pre-existing oedema, hypertension and renal function impairment - Ibuprofen may cause fluid retention and oedema.

Patients with uncontrolled hypertension, congestive heart failure (NYHA 11-111), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with IBUMOL BANANA 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.

Renal function impairment

Increased risk of adverse effects with prolonged use of high doses; occasional use is acceptable. Renal failure may be provoked, especially in patients with pre-existing renal impairment.

Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen medicines over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose. hypokalaemia and metabolic acidosis.

Allergies

Asthma may be exacerbated.

There is a possibility of cross-sensitivity with allergic conditions.

Haematological effects

There is an increased risk of bleeding IBUMOL BANANA can interfere with platelet aggregation and has been shown to prolong bleeding time in normal subjects. Anaemia may be exacerbated.

Hepatic function impairment

Increased risk of hepatotoxicity.

Elderly patients

The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding, ulceration and perforation (PUBs) which may be fatal. These patients are more likely to develop adverse hepatic or renal effects and if gastrointestinal ulceration or bleeding occurs is more likely to cause serious consequences.

Gastrointestinal effects

The risk of gastrointestinal bleeding, ulceration or perforation (PUBs) is higher with increasing doses of IBUMOL BANANA, in patients with a history of ulcers, and the elderly. When gastrointestinal bleeding or ulceration occurs in patients receiving IBUMOL BANANA, treatment with IBUMOL BANANA should be stopped.

IBUMOL BANANA 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.

Systemic lupus erythematosus (SLE)

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

Foetal toxicity

IBUMOL BANANA is contraindicated for use in pregnancy (see section 4.3.). Regular use of NSAIDs, as contained in IBUMOL BANANA during the third trimester of pregnancy, may result in oligohydramnios/foetal renal dysfunction or 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 (see sections 4.3 and 4.6).

Drug reactions with Eosinophilia and systemic symptoms (DRESS)

DRESS has been reported in patients taking NSAIDs such as IBUMOL BANANA. 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 BANANA and evaluate the patient immediately.

Dermatological effects

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

Masking of symptoms of existing infections

The antipyretic, analgesic and anti-inflammatory action of ibuprofen may mask symptoms of the occurrence or worsening of infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine 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.

Laboratory tests

Diabetic patients may experience false results with blood glucose tests.

Surgery

Possible enhanced bleeding if surgery is required.

Effect on female fertility

There is limited evidence that medicines which inhibit cyclo-oxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible

Excipients

Sorbitol Warning:

IBUMOL BANANA contains sorbitol and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take IBUMOL BANANA.

4.5. Interaction with other medicines and other forms of interaction

Paracetamol

- *Hepatotoxic medicines* - Increased risk of hepatotoxicity.
- *Enzyme inducing medicines* - Increased risk of hepatoxicity. Possible decrease in therapeutic effects of paracetamol.
- *Metoclopramide and domperidone* - Absorption of paracetamol may be accelerated.
- *Cholestyramine* - Absorption of paracetamol is reduced if given within one hour of cholestyramine.
- *Warfarin and other coumarins:* anticoagulant effect may be enhanced by prolonged regular daily use of
  paracetamol with increased risk of bleeding;
- *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 including, cyclooxygenase-2 selective inhibitors and aspirin, concomitantly could result in an increase in side effects.
- *Anticoagulants* - Enhancement of anticoagulant effect and the possibility of gastrointestinal ulceration or bleeding.
- *Antiplatelet medicines and selective serotonin reuptake inhibitors (SSRIs):* Increased risk of gastrointestinal bleeding, ulceration and perforation.
- *Alcohol, corticosteroids, clopidogrel, ticlopidine, bisphosphonates, oxpentifylline* - Increased

risk of gastrointestinal bleeding and ulceration.

- *Antidiabetic agents* - Hypoglycaemic effects of these medicines may be increased.
- *Digoxin* - Increase in serum digoxin concentrations.
- *Lithium* - Increase in the steady-state concentration of lithium.
- *Methotrexate* - Increased and prolonged methotrexate plasma concentration and an increased risk of methotrexate toxicity.
- *Nephrotoxic medicines e.g. ciclosporin* - Increased risk of nephrotoxicity.
- *Antihypertensives or diuretics* - Reduction or reversal of the antihypertensive effect may occur.
- *Bone marrow depressants* - The leucopenic and/or thrombocytopenic effects of these medicines may be increased.
- *Mifepristone:* IBUMOL BANANA should not be used for 8 to 12 days after mifepristone administration as ibuprofen can reduce the effect of mifepristone.
- *Quinolone antibiotics:* NSAIDs such as IBUMOL BANANA can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs such as IBUMOL BANANA and quinolones may have an increased risk of developing convulsions.
- *Zidovudine:* Increased risk of haematological toxicity when NSAIDs such as IBUMOL BANANA are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and IBUMOL BANANA.

4.6. Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and lactation have not been established. Non-steroidal anti-inflammatories are not recommended in the second and third trimesters because of possible adverse effects on the foetus, such as premature closure of the ductus arteriosus (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 BANANA is contraindicated during the third trimester of pregnancy.

Lactation

Ibuprofen:

IBUMOL BANANA can appear in breast milk in very low concentrations and 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

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

4.8. Undesirable effects

a) Summary of the safety profile

The most commonly adverse events observed with the use of ibuprofen as contained in IBUMOL BANANA 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 BANANA.

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		Angranulocytosis, thrombocytopenia, leucopenia and neutropenia.	Pancytopenia
Immune system disorders		Anaphylaxis, hypersensitivity reactions, cutaneous hypersensitivity reactions including, among others, skin rashes and	Severe cutaneous drug reactions (SCARs) including DRESS reaction, fixed drug eruptions (FDE) and drug-induced

		angioedema. Very rare cases of serious skin reactions have been reported.	hypersensitivity syndrome (DIHS).
Metabolism and nutrition disorders			High anion gap metabolic acidosis (due to pyroglutamic acidosis).
Respiratory, thoracic and mediastinal disorders:		Bronchospasm (more likely in asthmatics sensitive to aspirin or other NSAIDs).	

Post-marketing experience

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Immune system 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)
Blood and the lymphatic system disorders		Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.	
Immune system disorders	Hypersensitivity reactions consisting	Severe hypersensitivity	Respiratory tract reactivity comprising

	of urticaria and pruritus	reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock), hypotension (anaphylaxis, angioedema or severe shock).	asthma, aggravated asthma, bronchospasm or dyspnoea.
Metabolism and nutrition disorders			Decreased appetite, hypokalemia.
Nervous system disorders	Dizziness, headache	Nervousness, depression, drowsiness and headache, aseptic meningitis	Insomnia
Eye disorders		Blurred vision and other ocular reactions.	
Ear and labyrinth disorders		Tinnitus	
Cardiac disorders			Angina pectoris, cardiac failure (may be precipitated in compromised patients, cardiac arrhythmias) and oedema
Vascular disorders			Hypertension, Kounis syndrome
Gastrointestinal disorders	Nausea, abdominal cramps, pain, dyspepsia	Peptic ulceration, gastrointestinal bleeding, bloating, constipation, vomiting decreased appetite and diarrhoea. peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis	Exacerbation of colitis and Crohn's disease.
Hepatobiliary disorders		Hepatitis, liver disorders	Abnormalities of liver function test
Skin and subcutaneous tissue disorders	Various skin rashes	Sensitivity reactions resulting in reversible skin rash (which may be accompanied by fever and mucosal lesions) or blood disorders, pruritus, severe cutaneous adverse reactions	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP) Photosensitivity reactions pustulosis.

		(SCARs) (including Stevens-Johnson syndrome, erythema multiforme, exfoliative dermatitis and toxic epidermal necrolysis can occur).	
Renal and urinary disorders		Impairment of renal function, acute reversible renal failure and oedema, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.	Renal colic, renal insufficiency ureteric colic, dysuria renal tubular acidosis.
Investigations		Decreased haemoglobin levels.	

Post-marketing experience

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Skin and Subcutaneous Tissue Disorders			Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) [see Warnings and Precautions].
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

Symptoms

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.

Treatment

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 to10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Liver damage may become apparent within 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.
Cerebral oedema and non-specific myocardial depression have occurred.

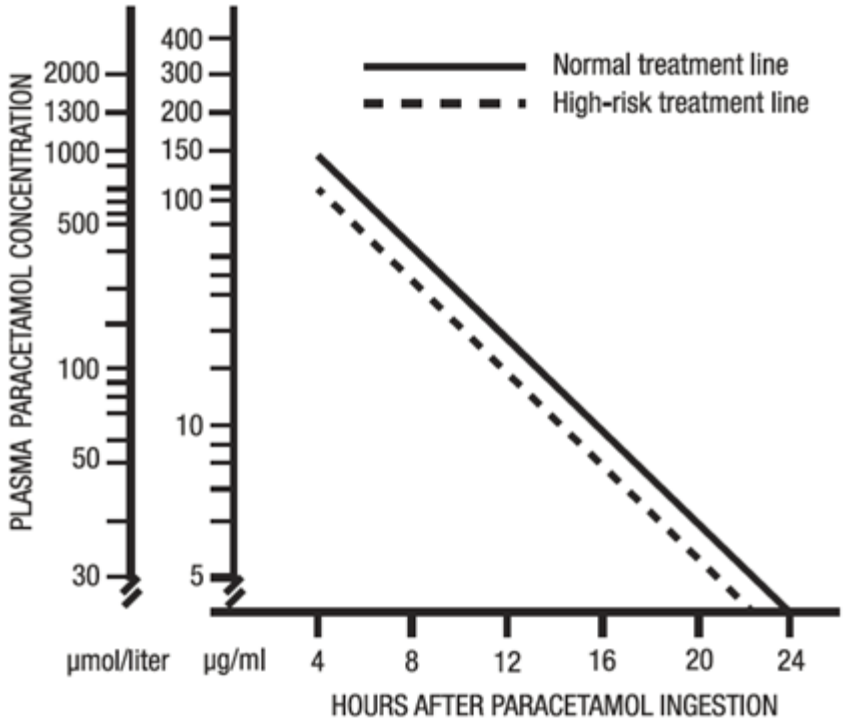
Although evidence is limited it is recommended that an adult who has ingested 5 g to 10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated 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, endotrachael intubation should precede gastric lavage to avoid aspiration.

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 is 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. If activated charcoal is used, then it should be removed by gastric lavage as it may interfere with absorption of orally administered acetylcysteine and decrease its efficacy.

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.



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

In children ingestion of more than 400mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Gastrointestinal symptoms (e.g. abdominal pain, nausea, vomiting), central nervous system symptoms (e.g. lethargy, drowsiness), gastrointestinal haemorrhage, acute renal failure, convulsions and coma. Tinnitus, headache and gastrointestinal bleeding are also possible.

In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. 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. Exacerbation of asthma is possible in asthmatics.

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).

Treatment

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

2.8 Analgesic combinations.

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

Paracetamol has analgesic and antipyretic effects.

Ibuprofen has analgesic, antipyretic and anti-inflammatory activities. Ibuprofen inhibits platelet aggregation.

5.2. Pharmacokinetic properties

Paracetamol:

Absorption following oral administration is well and 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, time to peak effect of 1 to 3 hours and a 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:

Well 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 4 to 6 hours for pain. More than 90 % of an ingested dose is excreted in the urine as metabolites or their conjugates. Protein binding of ibuprofen is more than 95 %.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carbopol, colour spectracol quinolone yellow (C.I. 4705), flavour banana, flavour tutti-frutti, glycerol, polysorbate, purified water, saccharin sodium, sodium benzoate, sodium cyclamate, sodium metabisulphite, sorbitol (70 %) solution.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

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

Protect from light.

Keep in original packaging until required for use.

6.5. Nature and contents of container

100 ml is packed into a round, amber glass bottle sealed with a white, tamper evident polypropylene duet screwcap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton.

100 ml is packed into a natural brown, round, high density polyethylene bottle sealed with a white, low density polyethylene (LDPE), snap-cap closure. The bottle is placed in an outer cardboard carton.

Not all packs and 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

0800 122 912

8. REGISTRATION NUMBER

A39/2.8/ 0228

9. DATE OF FIRST AUTHORISATION

25 November 2005

10. DATE OF REVISION OF TEXT

09 July 2026

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

Namibia: NS1 10/2.8/0628