1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

IBUMOL BANANA 250 mg/ 200 mg per 10 ml Suspension

Paracetamol and ibuprofen

Contains preservative: Sodium benzoate 0,1 % *m/v*

Contains sugar: Sorbitol 4,0 g and glycerol 630,5 mg per 10 ml

Contains sweetener: Sodium cyclamate 50 mg and saccharin sodium 7 mg per 10 ml

Read all of this leaflet carefully because it contains important information for you.

IBUMOL BANANA is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use IBUMOL BANANA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IBUMOL BANANA with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet:

1. What IBUMOL BANANA is and what it is used for

2. What you need to know before you take IBUMOL BANANA

3. How to take IBUMOL BANANA

4. Possible side effects

5. How to store IBUMOL BANANA

6. Contents of the pack and other information

1. What IBUMOL BANANA is and what it is used for:

IBUMOL BANANA contains ibuprofen and paracetamol as active ingredients. Ibuprofen belongs to a group of non-steroidal anti-inflammatory drug (NSAIDs), medicines which work by reducing pain, fever and swelling.

Paracetamol acts by relieving pain and fever.

IBUMOL BANANA is indicated for the short-term relief of mild to moderate pain of inflammatory origin with or without fever in children.

2. What you need to know before you take IBUMOL BANANA:

Do not take IBUMOL BANANA if you:

- are hypersensitive (allergic) to paracetamol, ibuprofen or any of the other ingredients of IBUMOL BANANA.
- have a history of gastrointestinal bleeding, ulceration or perforation (PUBs) related to IBUMOL BANANA or to any other NSAIDs treatment.
- have an active or history of recurrent gastrointestinal ulcer or haemorrhage or perforations.
- have cardiovascular disease, heart, liver or kidney failure.
- are sensitive to aspirin or another non-steroidal anti-inflammatory medicines (NSAIDs).
- have uncontrolled asthma or bronchospasm.
- have nasal polyps associated with aspirin-induced bronchospasm.
- are pregnant and in the last trimester of pregnancy, or breastfeeding.
- are receiving warfarin.

Warning and precautions:

IBUMOL BANANA contains paracetamol which may be fatal in overdose. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take special care with IBUMOL BANANA

- If you have a history of hypertension and/or heart failure as fluid retention and oedema (abnormal swelling from an accumulation of fluid beneath the skin) have been reported in association with IBUMOL BANANA therapy.
- If you suffer from SLE (a systemic autoimmune disease) or a similar condition.
- If you have impaired liver or kidney function.
- If you have a pre-existing disorders of blood coagulation (clotting) or anaemia (lower than normal number of red blood cells).
- If your treatment is prolonged your doctor should do regular blood counts and monitor your liver and kidney function. Depending on the results, your doctor may decide to discontinue your treatment.
- If you are an elderly patient, especially if you are a frail patient or have a low body mass (weight), your doctor may reduce your dosage.
- If you have a history of gastrointestinal (stomach) disease (e.g. ulcerative colitis (a form of bowel disease), Crohn's disease (inflammatory disease of the bowel and digestive tract), hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia (unexplained bleeding in the stomach) as the condition may be exacerbated.
- If you have serious skin reactions, which may be fatal, including exfoliative dermatitis (inflammatory skin disease), Stevens-Johnson syndrome, and toxic epidermal necrolysis (where the top layer of skin detaches from the lower layers) have been reported. IBUMOL BANANA should be discontinued at the first appearance of skin rash, mucosal lesions (sores), or any other sign of hypersensitivity or adverse reaction.
- Discontinue IBUMOL BANANA and consult your doctor if any of these serious skin reactions occur (some of which may be life threatening):
    - small, red or white skin eruptions (rash) with pus;
    - itchy blisters that may re-appear on the same spot;
    - skin rash with fever, facial swelling and/or abnormal heart rates;

- If you experience a life-threatening reaction resembling flu-like infection, with other symptoms such as skin rash, facial swelling, chest pain or irregular heartbeats, discontinue IBUMOL BANANA and consult your doctor immediately.
- If you have asthma or any other allergic condition.
- If you take IBUMOL BANANA for longer periods due to risk of kidney damage (signs include bone pain, muscle weakness and difficulty with passing urine).
- If you have severe infection, severe kidney or liver impairment, or you are malnourished as you be at risk of metabolic acidosis during treatment (indicated by deep and difficult breathing, feeling nauseous and loss of appetite), discontinue IBUMOL BANANA and tell your doctor immediately if you have these symptoms.
- If you are dependent on alcohol.
- If you are trying to conceive as IBUMOL BANANA may impair fertility in women, but this is reversible when treatment is stopped.

Other medicines and IBUMOL BANANA:

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

Tell your doctor if you are taking any of the following:

- Antiplatelet and anticoagulants (blood thinning tablets) such as aspirin or warfarin.
- Medicines to treat diabetes.
- Antihypertensives, beta blockers and diuretics.
- Antibiotics like levofloxacin and ciprofloxacin
- Lithium (used to treat some mental problems).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin or tacrolimus (used to treat some inflammatory diseases and after transplants).
- Digoxin used to treat heart problems.

- Medicines known as SSRIs used to treat depression.
- Oral steroids (an anti-inflammatory medicine for allergies).
- Another non-steroidal anti-inflammatory medicine.
- Mifepristone, a medication used in abortion.
- Zidovudine a medication used in HIV.
- The risk of gastrointestinal bleeding and ulceration is increased when used with alcohol, bisphosphonates or oxypentifylline.
- Enzyme inducing and hepatotoxic medicines (those that destroy liver cells).
- Metoclopramide and domperidone used as an antiemetic (medicine that relieves nausea and vomiting).
- Warfarin used for blood thinning
- Flucloxacillin (antibiotic for treating respiratory and skin infections)
- Cholestyramine used in reducing cholesterol levels in the blood.
- Probenecid used to treat gout.

Pregnancy, breastfeeding and fertility:

IBUMOL BANANA should not be used during the last trimester of pregnancy.

Avoid IBUMOL BANANA in the first 6 months of pregnancy and during breastfeeding.

IBUMOL BANANA may impair fertility in women, however, this is reversible upon cessation of treatment.

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 health care provider for advice before taking IBUMOL BANANA.

Driving and using machines:

Dizziness, drowsiness, fatigue and visual disturbances are possible after taking IBUMOL BANANA. If you experience any of these effects, you should not drive or operate machinery.

It is not always possible to predict to what extent IBUMOL BANANA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IBUMOL BANANA affects them.

IBUMOL BANANA contains sorbitol:

IBUMOL BANANA contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take IBUMOL BANANA.

3. How to take IBUMOL BANANA

Always take IBUMOL BANANA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person. Use the lowest effective dose for the shortest possible duration of treatment.

Adults and children over twelve years:

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.

Children six to twelve years old:

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

Children two to five years old:

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

IBUMOL should be taken preferably with or after food.

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

If no relief is obtained with the suggested dose, consult your physician. Do not use for longer than 7 days for pain or 3 days for fever.

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

If you take more IBUMOL than you should

IBUMOL BANANA contains paracetamol which may be fatal in overdose. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Immediate medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or poison centre.

In the first 24 hours include appearing pale, nausea, vomiting, strong fear of gaining weight (anorexia) and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage.

If you forget to take IBUMOL BANANA

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

IBUMOL BANANA can have side effects.

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

If any of the following happens, stop taking IBUMOL BANANA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions which can include skin rash, itching, bruising, painful red areas peeling or blistering, red or white blisters with pus, reappearance of rash on the same spot (hypersensitivity reactions);
- Life-threatening allergies resembling flu-like infection with symptoms like fever, facial swelling and/or abnormal heart rates;
- Wheezing or shortness of breath (bronchospasm);
- Swollen face, lips, hands or fingers;
- Stroke.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to IBUMOL BANANA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Any sign of bleeding in the stomach or intestine (bowel), for example, when emptying your

bowels, vomiting blood or black, tarry faeces;

- Yellowing of skin or the whites of your eyes, jaundice;
- Aseptic meningitis (inflammation of the tissues that cover the brain and spinal cord) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation;
- Heart failure may be precipitated in compromised patients, chest pain and irregular heartbeat;
- Peptic ulceration, perforation or gastrointestinal bleeding sometimes fatal;
- Impairment of kidney function and kidney failure and fluid retention;
- Metabolic acidosis (indicated by beathing difficulties, feeling nauseous or vomiting, loss of appetite);
- Painful urination or bloody urine;
- An unexpected change in the amount of urine produced and/or its appearance.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Dizziness;
- Skin rash;
- Itching;
- Nausea, abdominal cramps and pain;
- Indigestion, heartburn, wind, nausea (feeling sick), or vomiting (being sick).

Less frequent side effects:

- Inflammation of the nose;
- blood disorders like decrease in white blood cells, decrease in red blood cells;
- confusion, nervousness, sleeplessness, depression, anxiety, hallucination, drowsiness, blurred vision and other ocular (eye) reactions, ringing in the ears;
- indigestion, bloating, constipation, decreased appetite, diarrhoea and inflammation of the pancreas;
- abnormalities of liver function tests, inflammation of the liver;
- blood disorders, like decrease in white blood cells, decrease in red blood cells.

Side effects with an unknown frequency:

- Decreased appetite;
- Sensitivity reactions resulting in reversible skin rash;
- Kidney pain.

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 IBUMOL BANANA.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

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

5. How to store IBUMOL BANANA:

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

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information:

What IBUMOL BANANA contains:

The active substances are 200 mg ibuprofen and 250 mg paracetamol per 10 ml suspension.

The other ingredients are 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.

What IBUMOL BANANA looks like and contents of the pack:

A homogenous, yellow suspension with a sweet, fruity banana odour.

100 ml is packed in a round, amber, glass bottle with a white, tamper evident screw-cap. The bottle is placed in an outer cardboard carton together with a leaflet.

100 ml is packed in a brown high density polyethylene bottle with a white, low density polyethylene snap-cap closure. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of certificate of registration:

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 (0)11 239-6200

Registration number:

A39/2.8/ 0228

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Access to the corresponding Professional Information:

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

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