1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

IBUMOL 350 mg/ 200 mg tablets

Paracetamol and ibuprofen

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share IBUMOL 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 is and what it is used for

2. What you need to know before you take IBUMOL

3. How to take IBUMOL

4. Possible side effects

5. How to store IBUMOL

6. Contents of the pack and other information

1. What IBUMOL is and what it is used for

IBUMOL contains paracetamol and ibuprofen as active ingredients. Paracetamol acts by relieving pain and fever.

Ibuprofen belongs to a group of non-steroidal anti-inflammatory drugs (NSAIDs), medicines which work by reducing pain, fever and swelling.

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

2. What you need to know before you take IBUMOL

Do not take IBUMOL:

- If you are hypersensitive (allergic) to paracetamol or ibuprofen or any of the other ingredients of IBUMOL (listed in section 6).
- If you have a history of gastrointestinal perforations, ulceration or bleeding (PUBs) related to previous NSAIDs.
- If you have an active or history of recurrent gastrointestinal ulcers or haemorrhage or perforations.
- If you have heart or kidney failure.
- If you have severe liver impairment or liver failure.
- If you are sensitive to aspirin or other non-steroidal anti-inflammatory medicines (NSAIDs).
- If you have had an allergic reaction to NSAIDs.
- If you have uncontrolled asthma or bronchospasm (constriction of the airways).
- If you have nasal polyps (abnormal growths in projecting from the mucous membrane) associated with aspirin-induced bronchospasm.
- If you are pregnant.

Warnings and precautions

Take special care with IBUMOL:

- If you have a history of hypertension and/or heart failure as fluid retention and swelling may occur in association with IBUMOL 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 disorder of blood coagulation or anaemia.
- If your treatment is prolonged your doctor should do regular blood counts and monitor your hepatic and renal function. Depending on the results, your doctor may decide to discontinue your treatment.
- If you are elderly or if you are a frail patient or have a low body weight your dosage may need to be lowered.
- If you have a history of gastrointestinal diseases, as these conditions may be exacerbated e.g.:
    - Ulcerative colitis or Crohn's disease (a type of inflammatory bowel disease);
    - hiatus hernia (the protrusion of the upper part of the stomach into the thorax through a tear or weakness in the diaphragm);
    - gastro-oesophageal reflux disease (acid reflux disease);
    - angiodysplasia (a small vascular malformation of the gut).
- If you have serious skin reactions as serious skin conditions, some of them fatal, have been reported, including:
    - Small, red or white skin eruptions (rash) with pus;
    - Itchy blisters that may re-appear on the same spot;
    - Skin rash, accompanied by flu-like infection symptoms, fever, facial swelling and/or abnormal heart rates;

- Exfoliative dermatitis (scaly dermatitis of the skin);
- Stevens-Johnson syndrome and toxic epidermal necrolysis (often fatal diseases which cause sloughing of the skin). IBUMOL should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

- If you have asthma or any other allergic condition.
- If you take IBUMOL 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, kidney or liver impairment, or you are malnourished as you may be at risk of metabolic acidosis during treatment (indicated by deep and difficult breathing, feeling nauseous and loss of appetite), discontinue IBUMOL and tell your doctor immediately if you have these symptoms.
- If you are dependent on alcohol.

Other medicines and IBUMOL

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

- Medication that is toxic to the liver e.g. paracetamol,
- Medication used to treat gout like allopurinol,
- Methotrexate used to treat certain cancers or auto immune diseases.
- Metoclopramide and domperidone used as an anti-nausea medicine.
- 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.

The use of IBUMOL together with the following medicines may cause undesirable effects:

- Antiplatelet and anticoagulants (blood thinning tablets) such as aspirin or warfarin.
- Medicines to treat diabetes.
- Antihypertensives, beta blockers and diuretics.
- Aminoglycoside antibiotics.
- 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).
- Quinolone antibiotics (for infections).
- Digoxin, used to treat heart problems.
- Medicines used to treat depression.
- Oral steroids (an anti-inflammatory medicine).
- Another non-steroidal anti-inflammatory medicine.
- Mifepristone, a medication used in abortion.
- Zidovudine, a medication used in HIV.
- Bone marrow depressants e.g. medication that affect the immune system like azathioprine or medication used in the treatment of certain cancers.
- The risk of gastrointestinal bleeding and ulceration is increased when used with alcohol, bisphosphonates or oxypentifylline.
- Enzyme inducing medicines like certain anti-epilepsy medication like carbamazepine or medication used in the treatment of tuberculosis like rifampin.

Pregnancy, breastfeeding and fertility

The safety and efficacy when IBUMOL is used during pregnancy and lactation has not been established (see Do not take IBUMOL).

Do not take IBUMOL during the third trimester of pregnancy. Avoid IBUMOL in the first 6 months of pregnancy and when you are breastfeeding.

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.

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

Driving and using machines

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

It is not always possible to predict to what extent IBUMOL 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 affects them.

3. How to take IBUMOL

Always take IBUMOL 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.

The adult dose is one to two tablets three times a day, if necessary. Maximum of 6 tablets per day.

IBUMOL should be taken preferably with or after food.

Not recommended for children under 12 years of age.

If no relief is obtained with the suggested dose, consult your physician.

Do not use for longer than 10 days.

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

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

If you take more IBUMOL than you should

IBUMOL 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.

If you forget to take/missed a dose of IBUMOL

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

If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten dose.

4. Possible side effects:

IBUMOL can have side effects.

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

If any of the following happens, stop taking IBUMOL 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;
- swollen face, lips, hands or fingers;
- hypersensitivity reactions, some resembling flu-like infection with symptoms like fever, facial swelling and/or abnormal heart rates;
- wheezing or shortness of breath (bronchospasm);
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Severe cutaneous drug reactions (SCARs), including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), fixed drug eruptions (FDE), drug-induced hypersensitivity syndrome (DIHS), Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), erythema multiforme, exfoliative dermatitis and acute generalised xanthomatous pustulosis (AGEP).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to IBUMOL. 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, for example, when emptying your bowels, vomiting blood or black, tarry faeces;
- yellowing of skin or the whites of your eyes;
- aseptic meningitis 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 perforation, ulceration, gastrointestinal bleeding (sometimes fatal);
- abnormalities of liver function tests, inflammation of the liver, liver failure and jaundice;
- blood disorders like decrease in white blood cells (neutropenia, leucopenia), severe decrease in a particular type of white blood cells which makes infections more likely (agranulocytosis);
- increased number of a certain type of white blood cells in the blood (eosinophilia);
- decrease in red blood cells (anaemia);
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia);
- too few blood cells of all types; severe reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia);
- inflammation of the pancreas;
- muscle weakness, bone pain, fatigue, rapid breathing, and recurrent kidney stones as these are signs of renal tubular acidosis;
- extreme fatigue, muscle weakness, cramps, constipation, and heart palpitations as this might be signs of hypokalaemia;
- impairment in vision, eye pain that worsens with eye movement, blurred or dim vision

(optic neuritis);

- impairment in hearing;
- seeing or hearing things that are not there (hallucinations);
- an acute coronary syndrome triggered by a severe allergic reaction (Kounis syndrome) with symptoms such as chest pain, shortness of breath, nausea, vomiting, and light-headedness;
- exacerbation of colitis and Crohn's disease with symptoms such as abdominal pain, cramping diarrhoea and fatigue;
- kidney damage due to exposure to medicine (toxic nephropathy, interstitial nephritis, nephrotic syndrome and papillary necrosis), with symptoms such as reduced urine output, swelling, fatigue and nausea and vomiting;
- painful urination or bloody urine;
- impairment of renal function and renal failure and fluid retention.

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:

- Nausea (feeling sick), stomach pain, stomach cramps;
- dizziness.

The most commonly observed adverse events are gastrointestinal in nature.

Less frequent side effects:

- Runny nose, inflammation of the nose;
- nervousness, sleeplessness, drowsiness, headache;
- decreased haemoglobin levels;

- blurred vision and other ocular reactions;
- ringing in the ears;
- high blood pressure;
- indigestion, bloating, constipation, decreased appetite, diarrhoea;
- an unexpected change in the amount of urine produced and/or its appearance;
- respiratory tract reactivity comprising asthma, aggravated asthma, alveolitis.

Side effects with an unknown frequency:

- A sensation that the room is spinning (vertigo);
- confusion, anxiety, depression;
- feeling pins and needles (paraesthesia);
- a severe, painful inflammation inside the mouth (ulcerative stomatitis);
- an abnormal, exaggerated skin response to sunlight or UV radiation (photosensitivity reaction);
- pain that moves from the side (flank/loin) down to the lower abdomen with urinary changes (ureteric colic);
- pain, burning, or discomfort during urination (dysuria),
- headache, nausea, vomiting, dizziness, feeling weak or tired, loss of appetite and increased heartbeat due to high acidity in the body (high-anion gap metabolic acidosis).

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.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

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

By reporting side effects, you can help provide more information on the safety of IBUMOL.

5. How to store IBUMOL:

Store all medicines out of reach of children.

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

Protect from light and moisture.

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).

6. Contents of the pack and other information

What IBUMOL contains

The active substances are ibuprofen and paracetamol.

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

The other ingredients are magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch and purified talc.

Sugar free

What IBUMOL looks like and contents of the pack

IBUMOL is a round, white, biconvex tablet.

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.

Holder of certificate of registration

PHARMACARE LIMITED

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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

Tel: 0800 118 088

Botswana: B9309080 S3

Namibia: NS1 04/2.8/2014