SCHEDULING STATUS

S3

IBOFLAM, 200 mg coated tablets

Ibuprofen

Contains sugar:

Sucrose 35,424 mg per tablet

Lactose 112,08 mg per tablet

Read all of this leaflet carefully before you start taking IBOFLAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- IBOFLAM 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 IBOFLAM is and what it is used for

2. What you need to know before you take IBOFLAM
3. How to take IBOFLAM
4. Possible side effects
5. How to store IBOFLAM
6. Contents of the pack and other information

1. What IBOFLAM is and what it is used for

IBOFLAM contains ibuprofen. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines provide relief by changing the body's response to pain, inflammation and fever.

IBOFLAM is used to relieve pain and inflammation in adults and children over the age of 12 years in conditions such as:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Osteoarthritis
- Acute gouty arthritis
- Non-articular rheumatism including fibrositis.

2. What you need to know before you take IBOFLAM

Do not take IBOFLAM

- If you are hypersensitive (allergic) to ibuprofen or any of the other ingredients of IBOFLAM (listed in section 6).
- If you have peptic ulcer disease or gastrointestinal bleeding.
- If you are sensitive to aspirin or another non-steroidal anti-inflammatory medicines (NSAIDs).
- If you have a history of severe allergic reactions such as anaphylaxis (sudden, life-threatening severe allergic reaction) or angioedema, induced by aspirin or other NSAIDs because of the possibility of cross-sensitivity (due to structural relationships) which exist among non-steroidal anti-inflammatory medicines, acute allergic reactions are likely to occur in patients who have exhibited allergic reactions to these compounds.
- If you have nasal polyps (growths inside the nose) and bronchospasm (narrowing of air passages).
- Do not give to children under the age of 12 years.
- If you are in the last three months of pregnancy (see section 2 Pregnancy, breastfeeding, and fertility).
- If you have heart failure, liver failure or kidney failure.
- If you have a history of bleeding or erosion of the lining in the stomach or intestines, related to previous NSAIDs.

- If you have a history of repeat ulcers/bleeding/erosions.

Warnings and precautions

Take special care with IBOFLAM. You should talk to your doctor first before you take IBOFLAM.

- IBOFLAM may cover/disguise symptoms of an infection. If your symptoms stay or becomes worse, you should speak to your doctor.
- If you have high blood pressure or heart problems as IBOFLAM may increase your risk to have heart failure.
- If you are elderly, you might have an increased risk to experience side-effects, especially problems with your stomach or gut. Your doctor might suggest a lower dosage.
- If you have a history of ulcers (sores) or are elderly you have an increased risk of stomach ulceration, gastrointestinal bleeding or perforation (PUBs) (puncture of the intestinal track) with increasing doses of IBOFLAM. When gastrointestinal bleeding or ulceration occurs, you should stop taking IBOFLAM. (see section 4 Possible side effects).
- If you have a history of pain and discomfort (indigestion) in your gastrointestinal track or have a stomach or bowel disease. These conditions might get worse when you take IBOFLAM.
- If you have problems with your heart, liver or kidneys, you should be careful to take enough water as dehydration, e.g., after vomiting or diarrhoea, may further damage your kidneys.
- If you have a history of bleeding disorders, as IBOFLAM can prolong the time you bleed.
- If you have autoimmune disease, e.g., systemic lupus erythematosus (fatigue, joint pain, rash and fever) or mixed connective tissue disease (joint pain). IBOFLAM might increase your risk for meningitis (an inflammation (swelling of the protective membranes covering the brain and spinal cord).
- If you have or have a history of asthma or allergies, as you may experience bronchospasm (tightness of the chest and difficulty to breath) when you take IBOFLAM.
- If you take IBOFLAM at higher than recommended doses or for a long time, the potassium levels in your blood can become very low and your kidneys may become damaged which

affects their ability to remove acids properly from your blood into the urine (renal tubular acidosis). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Treatment with IBOFLAM may lead to side-effects, e.g., severe skin reactions. See section 4. POSSIBLE SIDE EFFECTS, for a list of side effects which you might experience and how to address it.

IBOFLAM contains sucrose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking IBOFLAM.

Other medicines and IBOFLAM

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

- Alcohol, corticosteroids (used for severe allergies and skin problems), clopidogrel (used to prevent heart attacks and strokes in persons with heart disease), ticlopidine (used to reduce the risk of thrombotic strokes), bisphosphonates (used for slowing bone loss), pentoxifylline (used to increase blood flow through narrow arteries). These medicines increase your risk of gastrointestinal bleeding and ulceration.
- Sulphonylurea such as glibenclamide (used to treat diabetes) as it may increase your risk to have low blood sugar.
- Digoxin as the digoxin levels can increase to dangerously high levels.
- Lithium (for depression) as lithium related side effects may be increased.
- Methotrexate for treating rheumatoid arthritis and some cancers) as the methotrexate levels can increase with a higher risk of having side effects relating.
- Ciclosporin and tacrolimus (used for the prevention of organ transplant) as this may lead to kidney impairment.

- Medicines for high blood pressure and water tablets as IBOFLAM may reduce their effect.
- Bone marrow depressants, e.g., chloramphenicol (an antibiotic), quinidine (used for irregular heartbeats), albendazole (used to treat certain tapeworm infections) and fenbendazole (used to treat a variety of parasites). These medicines can lower your white blood cell and platelet (used for blood clotting) levels.
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) as the use of IBOFLAM together with another NSAID could result in an increased risk of having side effects.

Medicines for treating blood clots (e.g., warfarin) as it may increase your risk of bleeding.

- Antidepressants known as selective serotonin reuptake inhibitors (SSRIs) as it may increase your risk of stomach bleeding.
- Quinolone antibiotics (e.g., levofloxacin used in the treatment of bacterial infections like pneumonia and other respiratory and urinary infections) as this may lead to seizures.
- Aminoglycosides (a type of antibiotic) as IBOFLAM may decrease the body's ability to remove aminoglycosides from the body which can lead to a dangerous build-up of aminoglycosides levels.
- Herbal extracts such as Ginkgo biloba as this may increase your risk of bleeding.
- Zidovudine (for treatment of HIV infection) as it may increase your risk of joint bleeds and/or swelling in people with haemophilia.
- Voriconazole or fluconazole (anti-fungal medicine) might increase IBOFLAM levels, and your doctor might lower your IBOFLAM dosage.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other health care provider for advice before you take IBOFLAM.

IBOFLAM is not recommended during pregnancy.

You should not take IBOFLAM in the last three months of your pregnancy or while you are breastfeeding.

You should not take IBOFLAM if you are planning to have a baby. IBOFLAM may make it more

difficult to become pregnant. However, this is reversible upon withdrawal of treatment.

Driving and using machines

It is not always possible to predict to what extent IBOFLAM may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which IBOFLAM affects you.

3. How to take IBOFLAM

Do not share medicines prescribed for you with any other person.

Always take IBOFLAM exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children over the age of 12 years

The recommended dosage of IBOFLAM is 400 – 600 mg (2 – 3 tablets) 6 to 8-hourly.

The total daily dose of IBOFLAM should not exceed 2 400 mg (12 tablets).

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

Children

This dosage form is not suitable for children below 12 years of age.

Method and route of administration

IBOFLAM should be swallowed with water. It should be taken with meals.

If you have the impression that the effect of IBOFLAM is too strong or too weak, talk to your doctor or pharmacist.

If you take more IBOFLAM than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you take IBOFLAM at higher than recommended doses or for a long time, the potassium levels in your blood can become very low and your kidneys may become damaged (renal tubular acidosis). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

If you forget to take a dose of IBOFLAM

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

IBOFLAM can have side effects.

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

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

- Aseptic meningitis, including fever, neck pain or stiffness, sensitive to light, headache.
- Feeling tired, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat, increase in nose bleeds or unusual bleeding (blood test shows changes in blood cell counts).
- Hypersensitivity reactions, including facial, tongue and throat swelling, dyspnoea, tachycardia, and hypotension.

- Severe blistering of the skin. These serious skin reactions include Stevens-Johnson syndrome, erythema multiforme and toxic epidermal syndrome, and acute generalised exanthematous pustulosis (AGEP).
- Drug Rash with Eosinophilia and Systemic Symptoms (DRESS syndrome): life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat.

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

Frequent side effects

- Headache, feeling dizzy.
- Heartburn, nausea, vomiting, constipation, diarrhoea, abdominal pain, flatulence, black stools, vomiting of blood, bleeding from the stomach or bowel.
- Skin rash
- Feeling tired

Less frequent side effects

- Running nose (rhinitis)
- Insomnia (hard to fall and/or stay asleep), anxiety, depression, feeling confused.
- Pins and needles, feeling sleepy.
- Visual loss in one or both eyes, changes in how you see colour
- Hearing loss, tinnitus (ringing sound in the ear), dizziness
- Heart disease: may have chest pain, fatigue, leg swelling and/or shortness of breath.
- High blood pressure
- Asthma, tightness of chest and difficult to breath
- Inflammation in the stomach or pancreas resulting in abdominal pain, ulcers in the mouth, stomach or bowels.

- Liver disease (you may have tummy pain and yellowing of the eyes and skin)
- Skin rash, itchy, red hives, severe skin reaction to the sun
- Kidney problems (you may have blood in your urine, cloudy urine, change in how frequent you want to urinate)
- Swelling of feet/legs and ankles

Frequency unknown

- Hypokalaemia (low levels of potassium in your blood)
- Colitis symptoms gets worse, e.g., bloody diarrhoea, abdominal cramping and pain on the left side, and urgency to defecate.
- Crohn's disease (inflammation of the digestive tract, which can lead to abdominal pain, fatigue, severe diarrhoea, and weight loss).
- Renal tubular acidosis (the kidneys are damaged and can't remove a waste, called acid, from the blood.)

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. This includes any possible side effects not listed in this leaflet. 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 IBOFLAM

5. How to store IBOFLAM

Store all medicines out of reach of children.

- Store in a cool dry place, at or below 25°C. Protect from light.
- Do not use after the expiry date stated on the label.
- Return all unused medicines to your pharmacist.

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

6. Contents of the pack and other information

What IBOFLAM contains

The active substance is ibuprofen.

Each tablet contains 200 mg ibuprofen.

The other ingredients are:

Tablet core

Ludipress® (lactose, Kollidon® 30 (povidone), Kollidon® CL (crospovidone)), magnesium stearate, microcrystalline cellulose, starch.

Coating

Wax formula: Carnauba wax, chloroform, white beeswax

Opalux pink colour: Mastercoat pink DSP0091 (FD&C Red No. 40 Al. Lake, Eurolake Erythrodine, Titanium Dioxide), sucrose

White smoothing cream: Calcium carbonate, gum acacia powder, sucrose, purified talc, titanium dioxide

Sealing solution: Ethanol 96,4 % *v/v,* Opadry® OY-28-0200 (polyvinyl acetate phthalate, stearic acid), talc

Gelatin: Gelatin, sucrose

What IBOFLAM looks like and contents of the pack

Pink, round, biconvex, sugar-coated tablets.

1 000 tablets in amber PVC bottles.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

This leaflet was last revised in

30 September 2023

Registration number

Z/3.1/377

Access to the corresponding Professional Information

Available on SAHPRA website