Patient Information Leaflet

SCHEDULING STATUS

S3

IBUNATE 200 mg TABLETS
Ibuprofen
Contains sugar: Lactose monohydrate 120,0 mg/tablet.

Read all of this leaflet carefully before you start taking IBUNATE 200 mg TABLETS
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- IBUNATE 200 mg TABLETS 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 IBUNATE 200 mg TABLETS is and what it is used for
2. What you need to know before you take IBUNATE 200 mg TABLETS
3. How to take IBUNATE 200 mg TABLETS
4. Possible side effects
5. How to store IBUNATE 200 mg TABLETS
6. Contents of the pack and other information

1. What you need to know before you take IBUNATE 200 mg TABLETS.
IBUNATE 200 mg TABLETS belongs to a group of medicines called anti-inflammatory pain killers (also called nonsteroidal anti-inframammary drugs (NSAIDs)).
The active ingredient, ibuprofen, has pain relieving, fever reducing and anti-inflammatory actions. Your doctor may prescribe IBUNATE 200 mg TABLETS for the symptomatic relief (relieving symptoms or effects but not dealing with the underlying cause of the symptom) of:
- Rheumatoid arthritis (chronic disease of the system, mainly inflammation of joints).
- Idiopathic juvenile arthritis (Still's disease) of children.
- Ankylosing spondylitis (immobility of a joint due to disease).
- Osteo-arthritis (a non-inflammatory change to a less active form of joints).
- Arthritis due to gout.
- Non-articular (non-joint) rheumatism including fibrositis (inflammation with pain and stiffness).
- Non-rheumatic inflammatory conditions such as frozen shoulder (capsulitis), bursitis (inflammation of sac like cavity filled with a liquid in the tissues), tendonitis (inflammation of the tendons), tenosynovitis (inflammation of the membranes of the tendon) and low back pain.
- Relief of mild to moderate pain such as painful menstruation, dental, after prevention of tearing during delivery and pain after childbirth.
- Soft tissue injuries such as sprains and strains.
- Fever.

2. What you need to know before you take IBUNATE 200 mg TABLETS
Do not take IBUNATE 200 mg TABLETS
- if you are hypersensitive (allergic) ibuprofen or any of the other ingredients of IBUNATE 200 mg TABLETS (listed in section 6),
- if you have heart failure,
- if you have stomach ulcer disease or gastro-intestinal bleeding,
- if you have a history of gastro-intestinal bleeding, ulcers or perforation related to previous anti-inflammatory pain killers (NSAIDs),
- if you are sensitive to aspirin or another nonsteroidal anti-inflammatory medicine,
- if you have a history of severe allergic reaction such as anaphylaxis or antioedema (allergic reactions with swelling of the face, lips, tongue and or throat with difficulty in swallowing or breathing), induced by aspirin or other NSAIDs,
- if you have aspirin-induced nasal protruding growths associated with bronchospasm,
- if you have asthma which has symptoms of breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest,
- if you have or ever had any history of kidney disease which has symptoms of little or no urine, drowsiness, nausea, vomiting, breathlessness (renal failure),
- you are pregnant, do not use IBUNATE 200 mg TABLETS at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause harm to your unborn baby,
- if you are or breastfeeding,
- if children are 12 years and younger.

Warnings and precautions
Take special care with IBUNATE 200 mg TABLETS
- if you have a history of high blood pressure and/or heart failure,
- if you have a history of peptic ulcers and other stomach or bowel disease,
- if you experience any unusual abdominal symptoms (especially bleeding from the stomach or bowel) during treatment with IBUNATE 200 mg TABLETS,
- if you are elderly, or suffer from asthma or bronchospasm, bleeding disorders, perforation in the digestive tract, heart disease and in liver or kidney failure,
- if you have a serious skin reaction, after taking IBUNATE 200 mg TABLETS,
- IBUNATE 200 mg TABLETS should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity,
- if you have an abnormal accumulation of fluid due to heart disease, cirrhosis (liver disease), volume depletion due to water tablets or kidney problems,
- if you are receiving anti-blood clotters (such as warfarin),
- if you experience blurred or diminished vision, or changes in colour vision,
- if you have a disease of the connective tissue, you may be at risk of developing aseptic meningitis (inflammation of the membranes of the brain),
- mild reactions such as allergic inflammation of the mucous membrane of the brain or skin rash induced by aspirin or other NSAIDs,
- if you have anaemia,
- if you have ulcers, sores, or white spots in mouth,
- if you have systemic lupus erythematosus (SLE),
- if you are pregnant, do not use IBUNATE 200 mg TABLETS at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid. Additionally do not use IBUNATE 200 mg TABLETS at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death,
- if you develop a skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

If you are taking IBUNATE 200 mg TABLETS for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Other medicine and IBUNATE 200 mg TABLETS
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Tell your doctor if you are already taking any of the following as they may interact with your medicine:
- Medicines that prevent blood from clotting (anti-coagulants or anti-platelet agents) – combination with IBUNATE 200 mg TABLETS can enhance the effects of the medication and make you prone to excessive bleeding.
- Alcohol, corticosteroids, clopidogrel, ticlopidine, bisphosphonates, pentoxifylline.
- Antidiabetic medicines.
- Aminoglycosides - (a type of antibiotic) - IBUNATE 200 mg TABLETS may decrease the body's ability to remove aminoglycosides from the body which can lead to a dangerous build-up of aminoglycosides levels.
- Aspirin - concomitant administration of IBUNATE 200 mg TABLETS and aspirin is not recommended because of the potential of increased adverse effects.
- Digoxin - IBUNATE 200 mg TABLETS may decrease the body's ability to remove digoxin from the body which can lead to a dangerous build-up of digoxin levels.
- Lithium - (used to treat mood disorders) - combination with lithium can disrupt the body's ability to remove lithium from the body which can lead to a dangerous build-up of lithium levels.
- Methotrexate.
- Immunosuppressive medicines e.g. ciclosporin - there is a small risk of experiencing kidney damage if you take IBUNATE 200 mg TABLETS while also taking ciclosporin.
- Medicines for high blood pressure including diuretics (medicine to help you pass water) - combination with IBUNATE 200 mg TABLETS may reduce the effect of anti-hypertensives, such as ACE inhibitors, beta-blockers and diuretics.
- Bone marrow depressants.
- Corticosteroids - (used in the treatment of inflammatory conditions) – concomitant use with IBUNATE 200 mg TABLETS increase the risk of gastrointestinal ulceration or bleeding.
- Medicines called selective serotonin reuptake inhibitors (typically used as antidepressants) - combination with a IBUNATE 200 mg TABLETS can increase the risk of you experiencing bleeding inside their digestive system.
- Any other non-steroidal anti-inflammatory medicines (NSAIDs) - always better to use one type of NSAID at a time to minimise the risks of side effects.
- Herbal extracts such as Ginkgo biloba - concomitant use with IBUNATE 200 mg TABLETS increases the risk of bleeding.
- Mifepristone – combination with IBUNATE 200 mg TABLETS causes a decrease in the efficacy of mifepristone.
- Quinolone antibiotics - taking IBUNATE 200 mg TABLETS and a quinolone class of antibiotic may increase the risk of you developing a seizure.

You may need to visit your doctor for more frequent checks if you are taking some of these medicines together with IBUNATE 200 mg TABLETS.

IBUNATE 200 mg TABLETS with food and drink
To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur, IBUNATE 200 mg TABLETS should be given with food or milk.

Pregnancy, breastfeeding and fertility
Pregnancy
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 IBUNATE 200 mg TABLETS.
Do not use IBUNATE 200 mg TABLETS at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.
Additionally do not use IBUNATE 200 mg TABLETS at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.
If taken late in pregnancy, may increase the length of pregnancy, prolong labour, or cause other problems during the delivery.

Driving and using machines
IBUNATE 200 mg TABLETS may cause dizziness, drowsiness, fatigue and visual disturbances.
If you experience this do not drive or operate any machinery.
IBUNATE 200 mg TABLETS contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take IBUNATE 200 mg TABLETS
Do not share medicines prescribed for you with any other person.
Always take IBUNATE 200 mg TABLETS exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.
Adults:
The usual dose is 6 – 12 tablets (1 200 mg to 2 400 mg) per day in divided doses.
Maintenance dose: 3 – 6 tablets (600 mg to 1 200 mg) per day in divided doses.
Do not take more than 6 tablets in 24 hours.
Take with food or milk.

If you take more IBUNATE 200 mg TABLETS than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
If you take an overdose, you may experience gastrointestinal effects such as nausea, vomiting and stomach pain.
Other symptoms include vomiting, dizziness, convulsion, loss of consciousness and depression of the central nervous system and respiratory system. Treatment is symptomatic and supportive.

If you forget to take IBUNATE 200 mg TABLETS
Do not take a double dose to make up for forgotten individual doses.
If you miss a dose of IBUNATE 200 mg TABLETS, take it as soon as you remember unless it is almost time for you next dose. If it is, do not take the missed dose at all.

4. Possible side effects:
IBUNATE 200 mg TABLETS can have side effects.
Not all side effects reported for IBUNATE 200 mg TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBUNATE 200 mg TABLETS, please consult your health care provider for advice.
If any of the following happen, stop taking IBUNATE 200 mg TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- rash or itching.

Immune disorders:
Less frequent: Aseptic meningitis (non-infectious inflammation of the membranes covering the brain), anaphylaxis (a severe, potentially life-threatening allergic reaction to something you're allergic to), fever, exacerbation of asthma and bronchospasm.

Gastrointestinal system disorders:
Frequent: nausea, vomiting, black stools, vomiting of blood, bleeding from the stomach or bowel, abdominal pain and dizziness.
Less frequent: abdominal discomfort or pain, gastrointestinal ulcers, sometimes with bleeding.
A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
These are all very serious side effects. If you have them, you may have had a serious reaction to IBUNATE 200 mg TABLETS. 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:
<u>Frequent side effects:</u>
- Dizziness,
- tinnitus (ringing sound in the ear).

<u>Less frequent side effects:</u>
- Acute renal failure,
- cystitis (inflammation of the bladder),
- haematuria (blood in urine),
- interstitial nephritis (swelling of the kidney),
- nephrotic syndrome (kidney disorder that causes your body to excrete too much protein in your urine),
- hepatotoxicity (liver damage),
- abnormalities in liver function tests,
- low blood cell count (anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis).

<u>Frequency unknown:</u>
- Visual impairment,
- changes in visual colour perception,
- toxic amblyopia (lazy eye syndrome),
- oedema (swelling), hypertension and cardiac failure.

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

Tell your doctor if you notice the following:
<u>Frequent side effects:</u>
- Indigestion,
- headache,
- constipation,
- diarrhoea,
- flatulence,
- nervousness,
- drowsiness,
- insomnia,
- depression.

<u>Less frequent side effects:</u>
- Abdominal discomfort or pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
IBUNATE 200 mg TABLETS, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.
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 "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 this IBUNATE 200 mg TABLETS. Alternately, please contact Gulf Drug Company (Pty) Ltd at +31 538 8700.

5. How to store IBUNATE 200 mg TABLETS
Store in a dry place at or below 25 ºC.
Protect from light.
Keep all medicines in a safe place, out of reach of children.
Return all unused or expired medicines to your pharmacist.
Do not dispose of unused medicine in the drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What IBUNATE 200 mg TABLETS contains:
The active ingredient is ibuprofen 200 mg per tablet.
The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose pH 102, Opadry II Pink/Flexicoate Pink V6 and pregelatinised starch.

What IBUNATE 200 mg TABLETS looks like and contents of the pack
Pink, round, biconvex, sugar coated tablets.
IBUNATE 200 mg TABLES are packed in containers with 20, 30, 100, 500 and 1000 tablets.

Holder of Certificate of Registration
Gulf Drug Company (Pty) Ltd
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Old Mill Industrial Park
Mount Edgecombe, 4300

This leaflet was last revised in
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Access to corresponding Professional Information
The Professional Information can be obtained from Gulf Drug Company (Pty) Ltd.
Please contact Gulf Drug Company (Pty) at +31 538 8700 or info@gulfdrug.co.za PIL/290727/1