PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

Ibuprofen 200 mg Clicks (200 mg ibuprofen) film coated tablets

Ibuprofen

Contains sugar (lactose monohydrate 8 mg/tablet).

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

Ibuprofen 200 mg Clicks is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Ibuprofen 200 mg Clicks carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Ibuprofen 200 mg Clicks with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What Ibuprofen 200 mg Clicks is and what it is used for
2. What you need to know before you take Ibuprofen 200 mg Clicks
3. How to take Ibuprofen 200 mg Clicks
4. Possible side effects
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1. What Ibuprofen 200 mg Clicks is and what it is used for

Ibuprofen 200 mg Clicks film coated tablets contain ibuprofen which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling and high temperature.

Each film-coated tablet contains 200 mg ibuprofen.

Ibuprofen 200 mg Clicks is used to treat:

- Soft tissue injuries such as sprains and strains
- headache
- back pain of musculoskeletal origin
- muscular aches and pain
- menstrual pain
- toothache
- pain associated with migraine
- earache

2. What you need to know before you take Ibuprofen 200 mg Clicks

Do not take Ibuprofen 200 mg Clicks:

- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients in Ibuprofen 200 mg Clicks (listed in section 6).
- if you have experienced asthma, skin rash or any allergic-type reaction after taking aspirin, ibuprofen or any other non-steroidal anti-inflammatory medicines**.**
- if you have a history of perforation or bleeding from the stomach or bowel related to previous use of a medicine belonging to a class of medicines called non-steroidal anti- inflammatory NSAID's.
- if you have or had a history of peptic ulceration, ulcerative colitis or Crohn's disease.
- if you have heart failure.
- if you have renal failure.
- if you are in your last trimester of pregnancy or during labour

Do not take Ibuprofen 200 mg Clicks and tell your doctor if any of these apply to you.

Warnings and precautions

Take special care with Ibuprofen 200 mg Clicks

- Speak to your doctor or pharmacist about all other medicines that you are taking. This includes other prescription medicines, medicines bought without a prescription, and herbal

medicines. Taking any other medicine together with Ibuprofen 200 mg Clicks may cause undesirable interactions.

- Speak to your doctor if you have any **other medical problems** such as asthma, high blood pressure, heart failure, a stomach ulcer, bleeding from the stomach or bowel or any other gastric complaint.
- If your body cannot tolerate milk and dairy products (lactose intolerant). Ibuprofen 200 mg Clicks contains lactose monohydrate and should not be given to patients with rare hereditary problems or history of galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption.
- 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 Ibuprofen 200 mg Clicks.

Serious skin reactions, some of them fatal, have been reported in association with the use of non-steroidal anti-inflammatory medicines such as Ibuprofen 200 mg Clicks. Ibuprofen 200 mg Clicks should be discontinued at the first appearance of skin rash, skin lesion or any other sign of hypersensitivity.

Children and adolescents

Not to be given to children under the age of 12 years.

There is a risk of renal impairment in dehydrated adolescents.

Other medicines and Ibuprofen 200 mg Clicks

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking

- Medicines for high blood pressure including diuretics (i.e. water pills) - combination with Ibuprofen 200 mg Clicks may reduce the effect of anti-hypertensives, such as ACE inhibitors, beta- blockers and diuretics

- Lithium salts and methotrexate - 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
- Medicines that prevent blood from clotting (anti-coagulants or anti-platelet agents) – combination with Ibuprofen 200 mg Clicks can enhance the effects of the medication and make you prone to excessive bleeding.
- Aspirin - concomitant administration of Ibuprofen 200 mg Clicks and aspirin is not recommended because of the potential of increased adverse effects
- Ciclosporin - there is a small risk of experiencing kidney and liver damage if you take Ibuprofen 200 mg Clicks while also taking ciclosporin
- Medicines known as corticosteroids (used in the treatment of inflammatory conditions) – concomitant use with Ibuprofen 200 mg Clicks increase the risk of gastrointestinal ulceration or bleeding
- Any other non-steroidal anti-inflammatory medicines - always best to use one type of NSAID at a time to minimise the risks of side effects
- Mifepristone – combination with Ibuprofen 200 mg Clicks causes a decrease in the efficacy of mifepristone
- Quinolone antibiotics - taking Ibuprofen 200 mg Clicks and a quinolone class of antibiotic may increase the risk of you developing a seizure.
- Tacrolimus - possible increased risk of kidney damage when Ibuprofen 200 mg Clicks is given with tacrolimus
- Zidovudine - Increased risk of blood toxicity when Ibuprofen 200 mg Clicks is given with zidovudine.
- Aminoglycosides (a type of antibiotic) – Ibuprofen 200 mg Clicks 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 - concomitant use with Ibuprofen 200 mg Clicks increase the risk of bleeding

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get new medicine. They can tell you if it is okay to take Ibuprofen 200 mg Clicks with other medicines.

Pregnancy and breastfeeding

You should not use Ibuprofen 200 mg Clicks in the last 3 months of pregnancy or during labour

You should not use Ibuprofen 200 mg Clicks when you breastfeed your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Ibuprofen 200 mg Clicks.

Driving and using machines

- Ibuprofen 200 mg Clicks may make you feel drowsy/sleepy, tired and disturb your vision.
- Do not drive because Ibuprofen 200 mg Clicks**,** could interfere with your ability to drive safely.
- Do not operate any tools or machines.

It is not always possible to predict to what extent Ibuprofen 200 mg Clicks 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 Ibuprofen 200 mg Clicks affects them.

Ibuprofen 200 mg Clicks contains lactose

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

Ibuprofen 200 mg Clicks and sodium content

IBUPROFEN 200 MG CLICKS contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Ibuprofen 200 mg Clicks

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

Usual dose of Ibuprofen 200 mg Clicks:

The lowest effective dose should be used and for the shortest possible duration.

Adults: The recommended dose is 1200 mg daily in divided doses (1 to 2 tablets every four hours) for the relief of:

1. Mild to moderate pain of

- Soft tissue injuries such as sprains and strains
- Toothache
- Back pain of musculoskeletal origin
- Earache
- Headache
- Pain associated with migraine
- Muscular ache and pains
- Fever
- Period pain

Children: Not to be given to children under 12 years of age.

If you take more Ibuprofen 200 mg Clicks than you should:

The most common symptoms of overdosage are pain in the upper middle part of the abdomen and nausea. Other symptoms include vomiting, dizziness, convulsion, loss of consciousness and depression of the central nervous system and respiratory system. Treatment is symptomatic and supportive.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take Ibuprofen 200 mg Clicks:

If you miss a dose of Ibuprofen 200 mg Clicks, take it as soon as you remember unless it is almost time for your next dose. If it is, do not take the missed dose at all. **DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR FORGOTTEN INDIVIDUAL DOSES.**

4. Possible side effects

Ibuprofen 200 mg Clicks can have side effects.

Not all side effects reported for Ibuprofen 200 mg Clicks are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Ibuprofen 200 mg Clicks, please consult your health care provider for advice.

If any of the following happens, stop taking Ibuprofen 200 mg Clicks and tell your doctor immediately or go to the casualty department at your nearest hospital:

Gastrointestinal system disorders:

The most frequent side effects of Ibuprofen 200 mg Clicks include indigestion, nausea, vomiting, constipation, diarrhoea, abdominal pain, flatulence, black stools, vomiting of blood, bleeding from the stomach or bowel, headache, dizziness and rash.

Less frequent: abdominal discomfort or pain, nausea, vomiting, gastro-intestinal ulcers, sometimes with bleeding.

Immune disorders:

Less frequent: Aseptic meningitis (non-infectious inflammation of the membranes covering the brain), angioedema (type of swelling that affects deeper layers in your skin, often around your eyes and lips), anaphylaxis (a severe, potentially life-threatening allergic reaction to something you're allergic to)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Ibuprofen 200 mg Clicks. 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:

Nervous system disorder:

Frequent: Dizziness, nervousness, tinnitus (ringing sound in the ear), drowsiness, insomnia

Less frequent: Headache, aseptic meningitis (inflammation of the brain)

Psychiatric disorder:

Frequent: Depression

Eye disorders:

Visual impairment, changes in visual colour perception, toxic amblyopia (lazy eye syndrome)

Renal and Urinary disorders:

Less frequent: 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), papillary necrosis (disorders of the

kidneys)

Hepatobiliary syndrome:

Less frequent: Hepatotoxicity (liver damage), abnormalities in liver function tests

Blood and lymphatic system disorders:

Less frequent: low blood cell count (Anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis)

Cardiovascular disorders:

Frequency unknown: Oedema (swelling), hypertension and cardiac failure.

Skin and subcutaneous tissue disorders:

Frequency unknown: Bullous reactions (sensitivity of the skin to the sun, blistering and swelling), including Stevens-Johnson syndrome and toxic epidermal necrolysis

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

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 the SAHPRA website.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of Ibuprofen 200 mg Clicks.

5. How to store Ibuprofen 200 mg Clicks

Store all medicines out of reach of children.

Store below 25 °C.

Do not take after the expiry date stated on the package.

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 Ibuprofen 200 mg Clicks contains

Ibuprofen 200 mg Clicks: The active substance is 200 mg ibuprofen.

The other ingredients are:

Cellulose Microcrystalline E460 (Avicel pH 101), Lactose Monohydrate, Croscarmellose sodium, Silica Colloidal Anhydrous, Croscarmellose sodium, Polyvinylpyrrolidone (PVPK-30), Maize Starch, Sodium lauryl sulphate, Magnesium Stearate E572.

Coating agent

Ready-for-use mixture containing: Hydroxy propyl cellulose E463, Hypromellose – 3cps E464, Hypromellose – 6cps E464, Macrogol 400, Titanium Dioxide E171, Isopropyl alcohol.

What Ibuprofen 200 mg Clicks looks like and contents of the pack

Ibuprofen 200 mg Clicks: White, circular, film-coated tablets, plain on both sides.

Ibuprofen 200 mg Clicks tablets are packed in White opaque PVC/ Aluminium blisters. The blisters are constructed of PVC (250 µ thickness) and Aluminium foil (0.02 mm thickness).

Ibuprofen 200 mg Clicks tablets are supplied in blister packs of 12, 20 and 24 tablets.

Holder of Certificate of Registration

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