PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BETAPROFEN® 200 TABLETS

Ibuprofen

Contains sugar: Sucrose: 84,3 mg per tablet and lactose: 102,74 mg per tablet

Read all of this leaflet carefully before you start taking BETAPROFEN® 200

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **BETAPROFEN® 200** 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 BETAPROFEN® 200 is and what it is used for

The active substance is Ibuprofen 200 mg per tablet.

Ibuprofen belongs to a group of medicines called Non-steroidal Anti-inflammatory Drugs that work by relieving pain, reducing swelling and fever.

You may have been prescribed **BETAPROFEN® 200** for the treatment of rheumatic & muscular pain and disease mainly affecting the joints with pain and swelling (osteoarthritis).

2. What you need to know before you take BETAPROFEN® 200

Do not take **BETAPROFEN® 200**

- If you are hypersensitive (allergic) to Ibuprofen or any of the other ingredients of **BETAPROFEN® 200** (listed in section 6)**.**
- 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 a disease of the heart and blood vessels
- If you have or ever had any history of pain and discomfort (indigestion) which is felt between the navel and the breast bone (peptic ulcer)
- If you have or ever had any history of bleeding disorders
- 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)
- If you are pregnant, do not use **BETAPROFEN® 200** at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because these medicines may cause harm in your unborn baby.

Warnings and precautions

Tell your doctor or health care provide before taking **BETAPROFEN® 200**:

Take special care with **BETAPROFEN® 200**:

- 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 **BETAPROFEN® 200**.
- If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal.
- If you have a serious skin reaction, after taking **BETAPROFEN® 200.**

  BETAPROFEN® 200 should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity.
- If you are using medications used for thinning of blood (coumarin anticoagulants)
- If you are pregnant, do not use **BETAPROFEN® 200** 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 **BETAPROFEN® 200** 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).

Some medicines contain codeine, which is an opioid medicine.

Repeated use of BETAPROFEN® 200 with opioid medicines may result in you becoming accustomed to it (needing to take higher doses). Repeated use of opioid

medicines together with BETAPROFEN® 200 may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you are taking opioid medicines together with BETAPROFEN® 200 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 stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

If you experience any of the following signs whilst taking these opioid medicines together with **BETAPROFEN® 200**, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this opioid medicine for longer than advised
- You need to take more of the opioid medicine than the recommended dose
- You are using this opioid medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of this opioid medicine
- When you stop taking this opioid medicine you feel unwell, and you feel better once taking this opioid medicine again ('withdrawal effects').

Other medicines and BETAPROFEN® 200

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

Tell your doctor or pharmacist if you are currently using:

- Medicines for high blood pressure including diuretics (medicine to help you pass water) - combination with **BETAPROFEN® 200** may reduce the effect of anti-hypertensives, such as ACE inhibitors, beta-blockers and diuretics.
- 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.
- Medicines that prevent blood from clotting (anti-coagulants or anti-platelet agents) – combination with **BETAPROFEN® 200** can enhance the effects of the medication and make you prone to excessive bleeding.
- Medicines called selective serotonin reuptake inhibitors (typically used as antidepressants) - combination with a **BETAPROFEN® 200** can increase the risk of you experiencing bleeding inside their digestive system.
- Aminoglycosides (a type of antibiotic) - **BETAPROFEN® 200** 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 **BETAPROFEN® 200** and aspirin is not recommended because of the potential of increased adverse effects.
- Digoxin - **BETAPROFEN® 200** may decrease the body's ability to remove digoxin from the body which can lead to a dangerous build-up of digoxin levels.
- Ciclosporin - there is a small risk of experiencing kidney damage if you take **BETAPROFEN® 200** while also taking ciclosporin
- Medicines known as corticosteroids (used in the treatment of inflammatory conditions) – concomitant use with **BETAPROFEN® 200** increase the risk of gastrointestinal ulceration or bleeding

- Any other non-steroidal anti-inflammatory medicines (NSAID) - 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 **BETAPROFEN® 200** increases the risk of bleeding
- Mifepristone – combination with **BETAPROFEN® 200** causes a decrease in the efficacy of mifepristone
- Quinolone antibiotics - taking **BETAPROFEN® 200** and a quinolone class of antibiotic may increase the risk of you developing a seizure.

BETAPROFEN® 200 with food, drink and alcohol

To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur, **BETAPROFEN® 200** should be given with food or milk.

Pregnancy, breast-feeding 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 **BETAPROFEN® 200**.

Do not use **BETAPROFEN® 200** 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 **BETAPROFEN® 200** 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.

Breast-feeding

You should not use **BETAPROFEN® 200** if you are breastfeeding.

Driving and using machines

BETAPROFEN® 200 may cause dizziness, drowsiness, fatigue and visual disturbances. If you experience this do not drive or operate any machinery.

BETAPROFEN® 200 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking **BETAPROFEN® 200.**

3. How to take BETAPROFEN® 200

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

Always take **BETAPROFEN® 200** exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for Adults is:

Acute: 1 200 mg to 2 400 mg per day in divided doses

Maintenance: 600 mg to 1 200 mg per day in divided doses

The total daily dose should not exceed 2 400 mg per day.

To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur, **BETAPROFEN® 200** should be given with food or milk.

If you have the impression that the effect of **BETAPROFEN® 200** is too strong or too weak, tell your doctor or pharmacist.

If you take more BETAPROFEN® 200 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. If recently taken, gastric lavage will remove any unabsorbed **BETAPROFEN® 200.**

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 BETAPROFEN® 200

If you miss a dose of **BETAPROFEN® 200**, 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

BETAPROFEN® 200 can have side effects.

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

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

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), Fever, rashes, exacerbation of asthma and bronchospasm

Gastrointestinal system disorders:

Frequent: nausea, vomiting, black stools, vomiting of blood, bleeding from the stomach or bowel, abdominal pain, dizziness and rash.

Less frequent: abdominal discomfort or pain, gastro-intestinal 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 allergic reaction to **BETAPROFEN® 200**. You may need urgent medical attention or hospitalisation.

Skin becomes sensitive to light:

BETAPROFEN® 200, 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.

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

Frequent side effects:

- dizziness,
- tinnitus (ringing sound in the ear),

Less frequent side effects:

- 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)

Frequency unknown:

- 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 :

Frequent side effects:

- indigestion,
- headache,
- constipation,
- diarrhoea,
- flatulence,
- nervousness,
- drowsiness,
- insomnia,
- depression.

Less frequent side effects:

- abdominal discomfort or 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 or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form",** found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of the product.

5. How to store BETAPROFEN® 200

Store all medicines out of reach of children.

Store in a cool (at or below 25 °C) dry place. Protect from light.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What BETAPROFEN® 200 contains

Each tablet contains 200 mg Ibuprofen

The other ingredients are:

Tablet Core

Ludipress, magnesium Stearate, microcrystalline Cellulose (Avicel)

starch 1500 (pregelatinised Starch)

Tablet Coating

- Dusting powder: acacia, calcium carbonate, purified talc, titanium dioxide
- Gelatin Solution: alcohol 96 % *v/v*, gelatin, nipastat, sucrose
- Opalux Pink Colour: opalux pink A.S 1181, syrup simplex (sucrose and purified water)
- Opaseal P17-0200: alcohol 96 % *v/v*, opadry oy-28-0200
- Polishing wax: carnuba wax, white beeswax
- Purified talc
- Solvent 45

What BETAPROFEN® 200 looks like and contents of the pack

Pink, round, biconvex, sugar-coated tablets.

Containers of 20, 30, 100, 500 and 1000 tablets.

Blister Pack of 20's.

Patient ready packs of different pack sizes.

Holder of Certificate of Registration

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