PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

BETAGESIC, 200 mg, film coated tablets

Ibuprofen

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share BETAGESIC 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 7 days.

What is in this leaflet.

1. What BETAGESIC is and what it is used for

BETAGESIC contains ibuprofen which belongs to a group of medicines referred to as non-steroidal anti-inflammatory medicines (NSAIDs). BETAGESIC is used for the relief of:

- Headaches from musculo-skeletal origin,
- Muscular aches and pain (originating from muscle and bone e.g., backache),
- Feverishness,
- Menstrual pain,
- Dental pain.

2. What you need to know before you take BETAGESIC

Do not take BETAGESIC

- If you are allergic to ibuprofen or any of the other ingredients of BETAGESIC tablets (listed in section 6).
- If you have heart failure.
- If you have bleeding disorder.
- If you have a heart problem.
- If you have peptic ulceration or a history of such ulceration.
- If you have history of gastric perforation or bleeding after having taken a different NSAID including BETAGESIC.
- Active or history of recurrent ulcer, haemorrhage, or perforations.
- If you are sensitive to aspirin.
- Severe kidney or liver problems.
- If you are pregnant, do not use BETAGESIC from 30 weeks of pregnancy onwards because it may cause kidney and heart problems in your unborn baby.

Warnings and precautions

Special care should be taken with BETAGESIC:

- If you are pregnant or planning to become pregnant consult your healthcare provider before taking BETAGESIC. Taking NSAIDs between 20 to 30 weeks of pregnancy may harm your

unborn baby. If you are prescribed NSAIDs by your healthcare provider when you are between 20 and 30 weeks of your pregnancy your healthcare provider may need to monitor the amount of fluid in your womb around your baby.

- If gastrointestinal bleeding or ulceration occurs while taking BETAGESIC, stop taking BETAGESIC.
- If you are prescribed NSAIDs by your health care provider when you are between 20 and 30 weeks of your pregnancy, limit BETAGESIC use to the lowest effective dose and shortest duration possible.
- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Discontinue treatment if these symptoms develop.
- If you have mild to moderate impaired (damaged) renal (kidney) function.
- Liver dysfunction.
- If you are receiving blood thinning medicines.
- If you have bleeding disorder.
- Do not take BETAGESIC with another type of NSAID.
- If you have history of hypertension (high blood pressure) and/or heart problems due to risk of fluid retention, oedema (swelling caused by fluid build in the body tissues), and heart failure.
- If you have significant risk factors for heart problems such as hypertension (high blood pressure), hyperlipidaemia, diabetes mellitus and smoking, take caution. You should be treated with diclofenac after careful consideration.
- if you are asthmatic or suffer from allergies. If you are suffering from asthma, consult with your doctor before taking BETAGESIC.
- If you are an elderly or you are giving BETAGESIC to an elderly person, due to increased risk of adverse reactions especially gastrointestinal perforation, ulceration, and bleeding.
- If you suffer from ulcers or you have history of ulcers.

- If you have history of gastrointestinal diseases (e.g., ulcerative colitis, [inflammation of the large intestine], Crohn's disease [an inflammatory disease affecting the gut], hiatus hernia [when part of your stomach moves up into your chest], gastro-oesophageal reflux disease [disease where stomach acid rises up into the oesophagus] and angiodysplasia [abnormality with the blood vessels in the gastrointestinal tract]), BETAGESIC can worsen the conditions.
- If you have history of gastrointestinal toxicity or you are giving BETAGESIC to an elderly person with history of gastrointestinal toxicity. Report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the first stages of treatment.
- If you have an infection since the symptoms such as fever and inflammation may be masked. Consult a doctor if symptoms persist or worsen.
- If you have systemic lupus erythematosus as BETAGESIC may cause meningitis or heart attack or stroke.
- If you develop serious skin reactions including exfoliative dermatitis (severe inflammation of the skin surface), Stevens-Johnson syndrome and toxic epidermal necrolysis (life threatening skin disorder causing rash, skin peeling and sores on the mucous membranes) and acute generalised exanthematous pustulosis (AGEP), a drug eruption characterised by superficial small skin lesions containing pus. Stop taking BETAGESIC at the first appearance of any sign of hypersensitivity.

Children and adolescents

Do not give BETAGESIC to children under the age of 12 years**.**

Other medicines and BETAGESIC

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

Caution is advised if you take BETAGESIC together with any of the following medicines:

- If you are taking aspirin, do not take BETAGESIC as ibuprofen has shown to interfere with the anti-clotting effect of aspirin and can increase risk of adverse reactions.
- NSAIDs: use of two or more NSAIDs together could result in an increase in side effects.
- Corticosteroids: increased risk of gastrointestinal perforation, ulceration, or bleeding (PUBs).
- Anti-coagulants (for treating blood clots) such as warfarin: BETAGESIC may increase the risk of bleeding.
- Anti-platelet medicines and selective serotonin reuptake inhibitors (antidepressants) (SSRIs): increased risk of stomach bleeding.
- Antihypertensives medicines (for high blood pressure) and diuretics (water tablets): their effects may be reduced if taken with NSAID medicines like BETAGESIC. Administering of this medicine may result in further deterioration of kidney function including possible short-term kidney failure which is usually reversible.
- BETAGESIC can make heart problems worsen, lower kidney function, and increase the levels of heart medication in your blood.
- Lithium (for depression); the lithium related side effects may increase.
- Methotrexate (for treating rheumatoid arthritis and some cancers): the side effects of methotrexate may increase.
- Ciclosporin and tacrolimus (used to prevent rejection of organ transplants) may lead to kidney impairment.
- Mifepristone (for terminating pregnancy): BETAGESIC reduces the effect of this medicine and should not be used for 8-12 days after mifepristone administration.
- Zidovudine (for the treatment of HIV): there is a risk of increased joint bleed and swelling in people with haemophilia.
- Quinolone antibiotics: taking quinolone antibiotics with BETAGESIC may lead to seizures.

BETAGESIC with food and drink and alcohol

No known interactions with food and drink and alcohol.

Pregnancy and breastfeeding and fertility

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 BETAGESIC.

Do not take BETAGESIC if you are pregnant for 30 weeks or more. **(**See **Section 2 "What you need to know before you take BETAGESIC")**.

If you are planning to have a baby, BETAGESIC may impair your ability to fall pregnant, but it is reversible if you stop taking BETAGESIC.

You should not take BETAGESIC if you are breastfeeding.

Driving and using machines

BETAGESIC may affect the ability to drive and use machines due to possible undesirable side effects such as drowsiness, dizziness, blurred eyesight, and other eyesight problems.

It is not always possible to predict to what extent BETAGESIC 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 BETAGESIC affects them

BETAGESIC contains methyl hydroxybenzoate

BETAGESIC contains methyl hydroxybenzoate and may cause allergic reactions (possibly delayed).

BETAGESIC contains propyl hydroxybenzoate

BETAGESIC contains propyl hydroxybenzoate and may cause allergic reactions (possibly delayed).

BETAGESIC contains sodium acetate trihydrate

This medicine contains less than 1 mmol sodium (23 mg) per 200 mg film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take BETAGESIC

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

Always take BETAGESIC exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 12 years of age and older

The recommended initial dose is 2 tablets orally with water, then if necessary, 1 or 2 tablets every four hours.

Do not take more than 6 tablets in 24 hours.

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

Use the lowest effective dose for the shortest duration of time necessary to relieve your symptoms.

If your symptoms continue for more than 7 days, consult your doctor.

If you take more BETAGESIC than you should

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

The most likely symptoms of overdosage are stomach pain and nausea.

If you forget to take BETAGESIC

Do not take a double dose to make up for forgotten doses.

4. Possible side effects

BETAGESIC can have side effects.

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

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

- Anaphylaxis indicated by swelling of mouth, throat and face or limbs and the inability to breathe;
- Asthma of worsening of your asthma;
- Allergic reaction such as rash, hives or itchy skin, low blood pressure (feeling faint);
- DRESS syndrome a life-threatening reaction which may resemble a flu-like infection or fever, skin rash, swelling of the lymph nodes and/or swelling of the face abnormal heartbeat.
- Severe skin reactions.

These are all very serious side effects. If you have them, you may have had a serious reaction to BETAGESIC. 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.

- Vomiting blood;
- Painful ulcers in your stomach and mouth;
- Bleeding in the gut;
- Liver disease (indicated by tummy pain and yellowing of the eyes and skin).

Tell your doctor if you notice any of the following:

Less frequent side effects

- Agranulocytosis (severe low white blood cells),
- Anaemia, neutropenia, eosinophilia, thrombocytopenia (Blood disorders);
- Hypersensitivity reactions consisting of urticaria (rash) and pruritis (itchy skin);

- Severe hypersensitivity reactions including facial, tongue and throat swelling, dyspnoea (difficulty breathing), tachycardia (increased heart rate/rapid heartbeat), and hypotension (anaphylaxis [sudden, severe allergic reaction], angioedema [rapid swelling under the skin], or severe shock);
- Headache and aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord);
- Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia (indigestion), abdominal pain;
- Peptic ulcers, perforation, or gastrointestinal bleeding, melaena (dark black tarry stools), haematemesis (vomiting blood), ulcerative stomatitis (inflammation of the mucous membrane lining of the mouth);
- Hepatotoxicity (liver damage caused by medication) and abnormalities in liver function tests;
- Skin rash, bullous reactions (fluid filled blisters), Stevens-Johnson Syndrome (serious disorder of the skin and mucous membranes), toxic epidermal necrolysis (severe skin reaction);
- Cystitis (inflammation of the bladder), haematuria (blood in urine), acute renal failure, interstitial nephritis (inflammation of the kidney), nephrotic syndrome (a condition where your kidneys leak too much protein into your urine).

Frequency unknown:

- Oedema (fluid build-up in the body tissues);
- Hypertension (high blood pressure);
- Heart failure;
- Provocation of bronchospasm (cause contraction of airways) in patients with asthma;
- Drug reaction with eosinophilia and systemic symptoms (DRESS)
- Acute generalised exanthematous pustulosis (AGEP), a drug eruption characterised by superficial small epidermal lesions containing pus (rare skin reactions);
- Photosensitivity reaction;

- Nervousness;
- Depression;
- Insomnia (difficulty sleeping);
- Drowsiness;
- Headache;
- Dizziness;
- Blurred vision and other visual field defects (blurred eyesight and other eyesight problems);
- Tinnitus (Ringing in the ear);
- Gastritis (inflammation of the stomach wall);
- Worsening of colitis and Crohn's disease (chronic disease that cause inflammation and irritation of the digestive tract);
- Impairment of renal function.

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 Med Safety APP (Medsafety x SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BETAGESIC.

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. How to store BETAGESIC

Store all medicine out of reach of children.

Store at or below 25 ºC.

Do not use after expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What BETAGESIC contains:

The active substance is Ibuprofen 200 mg.

Preservatives:

Methyl hydroxybenzoate 0,14 % *m/m*

Propyl hydroxybenzoate 0,06 % *m/m*

The other ingredients are Colloidal anhydrous silica, maize starch, stearic acid, Opadry pink 04A84530 (HPMC 2910/Hypromellose 15cP, light liquid paraffin, erythrosine aluminium lake, sodium acetate trihydrate, talc, titanium dioxide).

What BETAGESIC looks like and contents of the pack

Red coloured, circular, biconvex shaped, and film-coated tablets.

15's, 20's and 42's in PVC/Al blister packs.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

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