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

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 or 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

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PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS **S1**

BETAGESIC, 200 mg, filmbedekte tablette

Ibuprofeen

Suikervry

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u.

BETAGESIC is beskikbaar sonder 'n doktersvoorskrif vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds BETAGESIC versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie BETAGESIC met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter raadpleeg indien u simptome vererger of nie verbeter na 7 dae nie.

Wat in hierdie biljet is.

1. Wat BETAGESIC is en waarvoor word dit gebruik
2. Wat u moet weet voordat u BETAGESIC neem
3. Hoe om BETAGESIC te neem
4. Moontlike newe-effekte
5. Hoe om BETAGESIC te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat BETAGESIC is en waarvoor dit gebruik word

BETAGESIC bevat ibuprofeen wat behoort aan 'n groep medisyne wat nie-steroïed anti-inflammatoriese medisyne (NSAIMs) genoem word. BETAGESIC word gebruik vir die verligting van:

- Hoofpyn van muskuloskeletale oorsprong,
- Seer spiere en pyn (afkomstig van spiere en been, bv. rugpyn),
- Koorsigheid,
- Menstruele pyn,
- Tandpyn.

2. Wat u moet weet voordat u BETAGESIC neem

Moenie BETAGESIC neem nie

- Indien u allergies is vir ibuprofeen of enige van die ander bestanddele van BETAGESIC tablette (gelys in afdeling 6).
- Indien u hartversaking het.
- Indien u ‘n bloedingsversteuring het.
- Indien u ‘n hart probleem het.
- Indien u ‘n maagseer of 'n geskiedenis van sulke ulserasie het.
- Indien u 'n geskiedenis van maagperforasie of bloeding het nadat u 'n ander NSAIM geneem het, insluitend BETAGESIC.
- Aktiewe, of geskiedenis van herhalende ulkus, bloeding of perforasies.
- Indien u sensitief is vir aspirien.
- Erge nier- of lewerprobleme.
- Indien u swanger is, moenie BETAGESIC vanaf 30 weke van swangerskap gebruik nie, want dit kan nier- en hartprobleme by u ongebore baba veroorsaak.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met BETAGESIC:

- Indien u swanger is of van plan is om swanger te word, raadpleeg u gesondheidsorgverskaffer voordat u BETAGESIC neem. Die neem van NSAIMs tussen 20 en 30 weke van swangerskap

kan u ongebore baba benadeel. Indien NSAIMs deur u gesondheidsorgverskaffer aan u voorgeskryf word tussen 20 en 30 weke van u swangerskap, moet u gesondheidsorgverskaffer dalk die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor.

- Indien gastro-intestinale bloeding of ulserasie voorkom tydens die gebruik van BETAGESIC, hou op om BETAGESIC te neem.
- Indien NSAIMs deur u gesondheidsorgverskaffer aan u voorgeskryf word tussen 20 en 30 weke van swangerskap, beperk die gebruik van BETAGESIC tot die laagste effektiewe dosis en kortste moontlike duur.
- Indien u koors, veluitslag, swelling van die limfknope en/of swelling van die gesig ontwikkel. Dit staan bekend as geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS). Staak behandeling indien hierdie simptome ontwikkel.
- Indien u lig tot matig ingeperkte (beskadigde) renale- (nier) funksie het.
- Lewerdisfunksie.
- Indien u bloedverdunnende medisyne ontvang.
- Indien u bloedingsversteuring het.
- Moenie BETAGESIC saam met 'n ander tipe NSAIM neem nie.
- Indien u 'n geskiedenis van hipertensie (hoë bloeddruk) en/of hartprobleme het, as gevolg van die risiko van vloeistofretensie, edeem (swelling veroorsaak deur die opbou van vloeistof in die liggaamsweefsel) en hartversaking.
- Indien u beduidende risiko faktore vir hartprobleme het, soos hipertensie (hoë bloeddruk), hiperlipidemie, diabetes mellitus en rook, wees versigtig. U moet, na noukeurige oorweging, met diklofenak behandel word.
- indien u asmaties is of aan allergieë ly. Indien u aan asma ly, raadpleeg u dokter voordat u BETAGESIC neem.
- Indien u bejaard is, of u gee BETAGESIC aan 'n bejaarde persoon, as gevolg van verhoogde risiko van nadelige reaksies, veral gastro-intestinale perforasie, ulserasie, en bloeding.

- Indien u aan maagsere ly, of u het 'n geskiedenis van maagsere.
- Indien u 'n geskiedenis van gastro-intestinale siektes het (bv. ulseratiewe kolitis, [inflammasie van die dikderm], Crohn se siekte ['n inflammatoriese siekte wat die derms aantas], hiatusbreuk [wanneer 'n deel van u maag opdruk in u bors], gastro-esofageale refluksiekte [siekte waar maagsuur in die slukderm opstoot] en angiodisplasie [abnormaliteit met die bloedvate in die spysverteringskanaal]), BETAGESIC kan die toestande vererger.
- Indien u 'n geskiedenis van gastro-intestinale toksisiteit het of u gee BETAGESIC aan 'n bejaarde persoon met 'n geskiedenis van gastro-intestinale toksisiteit. Meld enige ongewone abdominale simptome aan (veral gastro-intestinale bloeding), veral in die vroeë stadiums van behandeling.
- Indien u 'n infeksie het, aangesien simptome soos koors en inflammasie verdoesel kan word. Raadpleeg 'n dokter indien simptome voortduur of vererger.
- Indien u sistemiese lupus eritematose het, aangesien BETAGESIC breinvliesontsteking of hartaanval of beroerte kan veroorsaak.
- Indien u ernstige velreaksies ontwikkel, insluitend afskilferende dermatitis (ernstige inflammasie van die veloppervlak), Stevens-Johnson sindroom en toksiese epidermale nekrolise (lewensgevaarlike velafwyking wat veluitslag, velafskilfering en sere op die slymvliese veroorsaak) en akute algemene eksantematiese pustulose (AAEP), 'n geneesmiddeluitslag wat gekenmerk word deur oppervlakkige klein velletsels wat etter bevat. Staak die gebruik van BETAGESIC met die eerste verskyning van enige teken van hipersensitiwiteit.

Kinders en adolessente

Moenie BETAGESIC aan kinders onder die ouderdom van 12 jaar gee nie**.**

Ander medisyne en BETAGESIC

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Wees versigtig indien u BETAGESIC saam met enige van die volgende medisyne neem:

- Indien u aspirien neem, moenie BETAGESIC neem nie, aangesien ibuprofeen getoon het dat dit inmeng met die anti-stollingseffek van aspirien en die risiko van nadelige reaksies kan verhoog.
- NSAIMs: die gebruik van twee of meer NSAIMs saam kan lei tot 'n verhoging in newe-effekte.
- Kortikosteroïede: verhoogde risiko van gastro-intestinale perforasie, ulserasie of bloeding (PUBs).
- Anti-stollingsmiddels (vir die behandeling van bloedklonte) soos warfarien: BETAGESIC kan die risiko van bloeding verhoog.
- Anti-bloedplaatjiemedisyne en selektiewe serotonien heropname inhibeerders (antidepressante) (SSHI's): verhoogde risiko van maagbloeding.
- Antihipertensiewe medisyne (vir hoë bloeddruk) en diuretika (watertablette): hul effekte kan verlaag word indien dit saam met NSAIMs soos BETAGESIC geneem word. Die toediening van hierdie medisyne kan lei tot verdere verswakking van nierfunksie, insluitend moontlike korttermyn nierversaking, wat gewoonlik omkeerbaar is.
- BETAGESIC kan hartprobleme vererger, nierfunksie verlaag en die vlakke van hartmedikasie in u bloed verhoog.
- Litium (vir depressie); die litium-verwante newe-effekte kan toeneem.
- Metotreksaat (vir die behandeling van rumatoïede artritis en sommige kankers): die newe-effekte van metotreksaat kan toeneem.
- Siklosporien en takrolimus (wat gebruik word om verwerping van orgaanoorplantings te voorkom) kan lei tot nierinkorting.
- Mifepristoon (vir die beëindiging van swangerskap): BETAGESIC verminder die effek van hierdie medisyne en moet nie vir 8-12 dae na mifepristoon-toediening gebruik word nie.
- Zidovudien (vir die behandeling van MIV): daar is 'n risiko vir verhoogde gewrigsbloeding en swelling by mense met hemofilie.

- Kinoloon-antibiotika: die neem van kinoloon-antibiotika met BETAGESIC kan tot stuipaanvalle lei.

BETAGESIC saam met kos en drank en alkohol

Geen bekende interaksies met kos en drank en alkohol nie.

Swangerskap en borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u BETAGESIC neem. Moenie BETAGESIC neem vanaf 30 weke van swangerskap nie. **(**Sien **Afdeling 2 "Wat u moet weet voordat u BETAGESIC neem").**

Indien u van plan is om 'n baba te hê, kan BETAGESIC u vermoë om swanger te raak verminder, maar dit is omkeerbaar indien u ophou om BETAGESIC te neem.

U moet nie BETAGESIC neem indien u borsvoed nie.

Bestuur en gebruik van masjinerie

BETAGESIC kan die vermoë om te bestuur en masjinerie te gebruik beïnvloed as gevolg van moontlike ongewenste newe-effekte soos slaperigheid, duiseligheid, versteurde visie en ander sigprobleme.

Dit is nie altyd moontlik om te voorspel in watter mate BETAGESIC die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie bogenoemde aktiwiteite verrig totdat hulle bewus is van die mate waartoe BETAGESIC hulle beïnvloed nie

BETAGESIC bevat metielhidroksibensoaat

BETAGESIC bevat metielhidroksibensoaat en kan allergiese reaksies veroorsaak (reaksie moontlik vertraag).

BETAGESIC bevat propielhidroksibensoaat

BETAGESIC bevat propielhidroksibensoaat en kan allergiese reaksies veroorsaak (vertraagde reaksie).

BETAGESIC bevat natriumasetaattrihidraat

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per 200 mg filmbedekte tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om BETAGESIC te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem BETAGESIC altyd presies soos beskryf in hierdie biljet of soos u dokter of apteker u vertel het.

Raadpleeg u dokter of apteker indien u nie seker is nie.

Volwassenes en kinders 12 jaar en ouer

Die aanbevole aanvanklike dosis is 2 tablette mondeliks met water, dan, indien nodig, 1 of 2 tablette elke vier uur.

Moenie meer as 6 tablette in 24 uur neem nie.

Moenie aan kinders jonger as 12 jaar gegee word nie.

Gebruik die laagste effektiewe dosis vir die kortste tydperk wat nodig is om u simptome te verlig.

Indien u simptome vir langer as 7 dae voortduur, raadpleeg u dokter.

Indien u meer BETAGESIC neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Die mees waarskynlike simptome van oordosering is maagpyn en naarheid.

Indien u vergeet om BETAGESIC te neem

Moenie 'n dubbele dosis neem om vergete dosisse op te maak nie.

4. Moontlike newe-effekte

BETAGESIC kan newe-effekte hê.

Nie alle newe-effekte wat vir BETAGESIC aangemeld is, is in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste effekte ervaar terwyl u BETAGESIC neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak gebruik van BETAGESIC en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Anafilakse aangedui deur swelling van mond, keel en gesig of ledemate en die onvermoë om asem te haal;
- Asma, of verergering van u asma;
- Allergiese reaksie soos veluitslag, galbulte of jeukerige vel, lae bloeddruk (flou voel);
- GRESS-sindroom, 'n lewensgevaarlike reaksie wat kan lyk soos 'n griepagtige infeksie of koors, veluitslag, swelling van die limfknope en/of swelling van die gesig, abnormale hartklop.
- Ernstige velreaksies.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op BETAGESIC gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk.

- Bloed braak;
- Pynlike sere in u maag en mond;
- Bloeding in die ingewande;
- Lewersiekte (aangedui deur maagpyn en vergeling van die oë en vel).

Lig u dokter in indien u enige van die volgende opmerk:

Minder gereelde newe-effekte

- Agranulositose (ernstige lae witbloedselvlakke),
- Bloedarmoede, neutropenie, eosinofilie, trombositopenie (Bloedafwykings);
- Hipersensitiwiteitsreaksies bestaande uit urtikaria (veluitslag) en pruritus (jeukerige vel);
- Erge hipersensitiwiteitsreaksies, insluitend swelling van die gesig, tong en keel, dispnee (moeilike asemhaling), tagikardie (verhoogde hartspoed/vinnige hartklop) en hipotensie (anafilakse [skielike, ernstige allergiese reaksie], angio-edeem [vinnige swelling onder die vel] of erge skok);
- Hoofpyn en aseptiese breinvliesontsteking (ontsteking van die membrane wat die brein en rugmurg omvou);
- Naarheid, braking, diarree, winderigheid, hardlywigheid, dispepsie (slegte spysvertering), buikpyn;
- Maagsere, perforasie of gastro-intestinale bloeding, melena (donkerswart teeragtige ontlasting), hematemese (braking van bloed), ulseratiewe stomatitis (inflammasie van die binnewand van die mond);
- Hepatotoksisiteit (lewerskade veroorsaak deur medikasie) en abnormaliteite in lewerfunksietoetse;
- Veluitslag, blaasvormende reaksies (vloeistofgevulde blase), Stevens-Johnson sindroom (ernstige afwyking van die vel en slymvliese), toksiese epidermale nekrolise (ernstige velreaksie);
- Sistitis (ontsteking van die blaas), hematurie (bloed in urien), akute nierversaking, interstisiële nefritis (inflammasie van die nier), nefrotiese sindroom ('n toestand waar u niere te veel proteïen in u urien deurlaat).

Frekwensie onbekend:

- Edeem (vloeistof wat opbou in die liggaamsweefsel);
- Hipertensie (hoë bloeddruk);
- Hartversaking;
- Uitlokking van brongospasma (veroorsaak sametrekking van lugweë) by pasiënte met asma;
- Geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS)
- Akute algemene eksantematiese pustulose (AAEP), 'n geneesmiddel-uitslag wat gekenmerk word deur oppervlakkige klein epidermale letsels wat etter bevat (seldsame velreaksies);
- Fotosensitiwiteitsreaksie;
- Senuweeagtigheid;
- Depressie;
- Slapeloosheid (probleme om te slaap);
- Lomerigheid;
- Hoofpyn;
- Duiseligheid;
- Versteurde visie en ander gesigsvelddefekte (versteurde sig en ander sigprobleme);
- Tinnitus (lui in die oor);
- Gastritis (inflammasie van die maagwand);
- Verergering van kolitis en Crohn se siekte (chroniese siekte wat inflammasie en irritasie van die spysverteringskanaal veroorsaak);
- Inperking van nierfunksie.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter of apteker. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety x SAHPRA) en elektroniese aanmeldingsplatform (who-

umc.org) wat op die SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BETAGESIC te verskaf.

U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-pos te gebruik: Adcock.AEReports@adcock.com

5. Hoe om BETAGESIC te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre teen of benede 25 ºC.

Moenie gebruik ná die vervaldatum wat op die etiket vermeld word nie.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat BETAGESIC bevat:

Die aktiewe bestanddeel is Ibuprofeen 200 mg.

Preserveermiddels:

Metielhidroksibensoaat 0,14 % *m/m*

Propielhidroksibensoaat 0,06 % *m/m*

Die ander bestanddele is kolloïdale watervrye silika, mieliestysel, stariensuur, *Opadry* pienk 04A84530 (HPMC 2910/Hipromellose 15cP, ligte vloeibare paraffien, eritrosien aluminiumlak, natriumasetaattrihidraat, talk, titaandioksied).

Hoe BETAGESIC lyk en inhoud van die verpakking

Rooikleurige, ronde, bikonveks-vormige en filmbedekte tablette.

15's, 20's en 42's in PVC/Al-stulpverpakkings.

Nie alle verpakkingsgroottes word dalk bemark nie.

PASIËNT INLIGTINGSBILJET

Houer van Registrasiesertifikaat

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