1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DECLOZIT 200 mg/30 mg film-coated tablets

Ibuprofen, pseudoephedrine

Contains sugar: Lactose monohydrate 6,7 mg

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

DECLOZIT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use DECLOZIT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DECLOZIT with any other person.
- Ask your healthcare 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 DECLOZIT is and what it is used for
2. What you need to know before you take DECLOZIT
3. How to take DECLOZIT
4. Possible side effects
5. How to store DECLOZIT
6. Contents of the pack and other information

1. What DECLOZIT is and what it is used for

DECLOZIT is a combination of two main ingredients: ibuprofen and pseudoephedrine hydrochloride. Ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory medicines (known as NSAIDs), which reduce fever and relieve pain. The other active ingredient pseudoephedrine hydrochloride is a decongestant, which relieves nasal congestion.

DECLOZIT is used to relieve the symptoms of common cold, sinusitis (swelling of the sinuses), or flu. These symptoms include nasal congestion, headache, fever, body aches and pain.

2. What you need to know before you take DECLOZIT

Do not take DECLOZIT:

- If you are hypersensitive (allergic) to ibuprofen, pseudoephedrine, or similar medicines used to treat colds and flu, or any of the other ingredients of DECLOZIT (listed in section 6).
- If you had a severe allergic reaction to aspirin, such as asthma attacks, swelling, shock or hives in the past.
- If you have heart conditions or if you had a heart attack in the past (myocardial infarction).
- If you have high blood pressure (hypertension).
- If you have a condition which causes high blood sugar levels (diabetes mellitus).
- If you have an overactive thyroid (hyperthyroidism).
- If you have a tendency to be easily and excessively excited (hyperexcitability).
- If you have an enlarged prostate (prostatic hypertrophy).
- If you have a tumour on your adrenal gland (phaeochromocytoma).
- If you have high pressure within your eye/s (glaucoma).
- If you have a history of fits (seizures).

- If you have an inflammatory disease caused when the immune system attacks its own tissues (systemic lupus erythematosus).
- If you have a history of stroke or risk factors for stroke.
- If you suffer from kidney or severe liver problems.
- If you have a history of stomach or intestinal bleeding, wounds in the stomach or intestines (ulceration) or tears in the stomach or intestines (perforation) related to using similar medicines in the past.
- If you have, or had in the past, ulcers, bleeding in the stomach or intestine (haemorrhage) or tears in the stomach or intestines (perforations).
- If you have bleeding problems or problems with blood clots.
- If you are pregnant do not use NSAIDs, including DECLOZIT at 30 weeks or later in your pregnancy unless specifically advised to do so by your healthcare professional because these medicines may cause problems in your unborn baby (see section titled Pregnancy, breastfeeding and fertility).
- If you are breastfeeding your baby.
- If you are taking monoamine oxidase inhibitor antidepressant treatment (medicine prescribed for depression, psychiatric or emotional conditions or Parkinson's disease), or if you stopped this treatment less than 14 days ago (see Other medicines and DECLOZIT).
- If you are taking any other cold and flu medicines (see Other medicines and DECLOZIT).

DECLOZIT is not suitable for children under 12 years.

Warnings and precautions

Take special care with DECLOZIT:

- You should not take other similar medicines containing ibuprofen or pseudoephedrine while taking DECLOZIT. Check with your doctor or pharmacist if you are unsure.
- DECLOZIT can cause bleeding, ulcer of tear in the stomach or intestines at any time, even if you did not have a history of these problems. Tell your doctor immediately if you notice blood in your stools or in your vomit, paleness, stomach pains or cramps, tiredness or black tarry stools.
- If you are elderly, you may have a higher risk of the above stomach or digestive tract side effects.
- Tell your doctor if you are taking other medicines which could put you at higher risk of the above stomach or intestinal side effects, such as blood thinners (warfarin), certain antidepressants such as citalopram, or aspirin (see section Other medicines and DECLOZIT).
- Tell your doctor if you notice changes in the way you see, such as blurred vision, loss of sight or changes in colour vision.
- Tell your doctor if you suffer from asthma, as DECLOZIT may cause an asthma attack or difficulty breathing (bronchospasm).
- If you suffer from headaches, taking DECLOZIT for a long time can make your headaches worse. Tell your doctor if you notice your headaches becoming worse.
- DECLOZIT may put you at risk for a stroke or heart attack so if you have a history of heart problems, or problems with your blood flow especially blood flow to your brain, if you smoke, or if you have high cholesterol levels, you should avoid taking DECLOZIT (see section Do not take DECLOZIT).
- DECLOZIT can hide (mask) symptoms of infection, which could delay treatment of the infection and thus could make the infection worse. Tell your doctor if you notice symptoms of an infection, such as fever, chills, sore throat, stiff neck, burning urine or any other signs of infection.

- If you have serious skin reactions, including exfoliative dermatitis (red and scaly skin), Drug Rash with Eosinophillia and Systemic Symptoms (DRESS), Stevens-Johnson syndrome and toxic epidermal necrolysis (life-threatening conditions causing shedding of the skin). DECLOZIT should be discontinued immediately at the first appearance of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity. You should also contact your doctor as soon as possible.
- DECLOZIT may affect the blood flow to your intestines (ischaemic colitis). Tell your doctor if you notice signs such as stomach pain, bleeding from your rectum or loose stools, with a fever.
- If you have a history of mental illness (psychosis).
- if you start seeing or hearing things that are not there (hallucinations), feeling restless or have sleep disturbances, tell your doctor.
- DECLOZIT may cause inability to urinate (urinary retention) in patient suffering from an enlarged prostate gland (prostatic hypertrophy).
- If you are planning to go for an operation or procedure where you will be made to sleep (sedated) or made to feel numb with anaesthetic, tell your doctor as you should stop taking DECLOZIT a few days before the operation.
- DECLOZIT can lead to positive results in doping tests. This may affect you if you are an athlete.
- DECLOZIT could affect blood test results. Speak to your doctor if you are concerned.
- If you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days 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. You should not take NSAIDs around 30 weeks of pregnancy or later.

Children and adolescents

There is no experience with DECLOZIT in children younger than 12 years.

Other medicines and DECLOZIT

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Other NSAIDs, including salicylates and COX-2 selective inhibitors: other medicines which also treat pain, fever and swelling (inflammation).
- Digoxin and other cardiac medicines (e.g. quinidine): medicines used to treat a variety of heart conditions.
- Corticosteroids (e.g. prednisone): medicines that lessen swelling, itching, redness or other allergic reactions.
- Acetylsalicylic acid (also known as aspirin): medicine used to treat pain, fever or swelling (inflammation).
- Anticoagulants (e.g. warfarin, ticlopidine, clopidogrel, tirofiban, eptifibatide, abciximab, iloprost, heparin): medicines used to treat blood clots.
- Anti-platelet medicines: medicines used to prevent blood clots from forming.
- Phenytoin: medicine used to treat recurrent fits (epilepsy).
- Selective serotonin reuptake inhibitors (SSRIs) (e.g. citalopram, fluoxetine): medicines used to treat depression.
- Lithium: medicine used to treat bipolar disorder, a type of mental illness.
- Probenecid and sulfinpyrazone: medicines used to treat a condition called gout where there is too much uric acid in the blood.

- Methotrexate: a medicine used to treat certain types of cancer, and severe psoriasis or rheumatoid arthritis.
- Ciclosporin: medicine used to reduce pain, swelling and stiffness in rheumatoid arthritis.
- Tacrolimus: medicine used to prevent rejection of a kidney, heart, or liver transplant.
- Zidovudine: medicine used to treat viral infections.
- Sulphonylureas (e.g. glibenclamide, gliclazide): medicines used to control blood sugar levels in patients with diabetes.
- Quinolone antibiotics (e.g. ciprofloxacin): medicines used to treat bacterial infections.
- Gingko biloba: a natural medicines used to treat a variety of ailments such as dizziness, memory loss premenstrual syndrome and other illnesses.
- Oral antidiabetic medicines and insulin: medicines used to lower high blood sugar levels in patients with diabetes.
- Bisphosphonates: medicines used to treat thinning of the bone, in osteoporosis.
- Oxpentifylline: medicine used to improve blood flow.
- Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide, iproniazid): medicines used to treat depression. Tell your doctor or healthcare provider if you are currently taking MAOIs or have taken MAOIs in the past 14 days (see section Do not take DECLOZIT).
- Other medicines used to treat nasal congestion or similar symptoms of colds and flu.
- Linezolid: medicine used to treat bacterial infections.
- Ergot alkaloids: Medicine used to treat severe, throbbing headaches, such as migraine and cluster headaches.

- Oxytocin: Medicine used to induce labour or strengthen uterine contractions, or to control bleeding after childbirth.
- Anaesthetics (e.g. halogenated anaesthetics, halothane): medicines used to make you feel numb before a surgical procedure.
- Levodopa: medicine used to manage Parkinson's symptoms such as tremors, stiffness, and slowness of movement.
- Tricyclic antidepressants (e.g. imipramine or amitriptyline): medicines used to treat depression.
- Antihypertensives (e.g. beta-blocking medicines and debrisoquine, guanethidine, reserpine, methyldopa, captopril): medicines used to treat high blood pressure.
- Diuretics (also known as ‘water tablets’): medicines that help lower the amount of water and salt in the body, thus helping to lower blood pressure.
- Citrates: medicines used to make urine less acidic and prevent kidney stones.
- Central nervous system (CNS) stimulants (e.g. atomoxetine, modafinil): medicines that cause you to feel alert and active.
- Nitrates: medicines used for treating or preventing heart pain (angina, chest pain) caused by heart disease.
- Thyroid medicines: medicines used to treat thyroid conditions.

DECLOZIT with alcohol

Alcohol should be avoided while taking DECLOZIT as you may be at risk for worsened side effects.

Pregnancy, breastfeeding and fertility

You should not take DECLOZIT if you are pregnant or breastfeeding your baby (see section Do not take DECLOZIT).

DECLOZIT can cause serious harm to your baby, may affect your labour and may cause a miscarriage.

If you take DECLOZIT during pregnancy, it 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 develop. Complications can occur with low levels of this fluid.

Talk to your doctor, nurse or pharmacist if you have questions or concerns about DECLOZIT or which medicines are similar to it.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

DECLOZIT may cause dizziness, seeing or hearing things that are not there (hallucinations), severe headaches and changes in the way you see or hear, which can affect your ability to drive or use machines.

It is not always possible to predict to what extent DECLOZIT may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DECLOZIT affects you (see section 4).

DECLOZIT contains lactose monohydrate

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free**'.**

3. How to take DECLOZIT

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

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

The usual dose of DECLOZIT is:

Adults and children 12 years and older:

Take one tablet every 4 to 6 hours. If symptoms do not respond to one tablet, a second tablet may be taken. Do not take more than 6 tablets in 24 hours.

DECLOZIT should be taken with a glass of water, with food or after meals.

Do not take for cold for more than 7 days or for fever for more than 3 days, unless directed by a doctor. If the cold or fever persists or gets worse, or if new symptoms occur, consult a doctor.

Use the lowest effective dose for the shortest possible duration of treatment.

If you take more DECLOZIT than you should

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

If you forget to take DECLOZIT

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

If you have missed a dose of DECLOZIT, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

DECLOZIT can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- sudden pus-filled blisters appearing on your skin, as this may be dues to a serious allergic reaction known as Acute generalised exanthematous pustulosis (AGEP).

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

- Worsening of infections such as necrotising fasciitis, a serious bacterial infection that destroys tissue under the skin, with symptoms such as blisters, fever, tiredness, and pain,
- worsening of infections such as aseptic meningitis, a swelling within the brain and spinal cord, with symptoms such as stiffness of the neck, headache, nausea, vomiting or fever,
- blood disorders which are usually detected in blood tests, but may be seen as pale skin, tiredness, fever, sore throat and mouth, small red spots on the skin, bruising or prolonged bleeding after injury. Blood disorders (such as agranulocytosis, leukopenia, haemolytic anaemia, ecchymoses) may be seen with symptoms of severe chills, mouth ulcers, headache, shortness of breath and dizziness (blood dyscrasias),
- fits (convulsions),
- damage to the nerve in the eye (toxic amblyopia), which shows symptoms such as a blind spot which becomes larger,
- damage to the nerve in the eye (ischaemic optic neuropathy), which shows symptoms such as pain in the eyes, loss of vision, flashing lights, double vision,
- stomach ulcers (peptic ulcers), tearing in the stomach or intestines (perforation), bleeding in the stomach or intestine (gastrointestinal bleeding), with symptoms such as blood in your stools or in your vomit, paleness, stomach pains or cramps, tiredness or black tarry stools,
- tightness of the chest, changes in the way your heart beats (dysrhythmias), for example, if you notice it beating faster (tachycardia),
- heart failure (cardiac arrest), heart attack (myocardial infarction), with symptoms such as severe chest pain, difficulty breathing, coughing, tiredness,
- chest pain (angina pectoris), or chest tightness with difficulty breathing (pulmonary oedema),

- swelling in the lungs (alveolitis), collection of white blood cells in the lungs (pulmonary eosinophilia), pulmonary oedema, with symptoms such as difficulty breathing, chest pain, coughing and tiredness,
- inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis),
- abnormal tiredness, dark urine, stomach pain and yellowing of the eyes and skin (jaundice). These may be signs of inflammation in the liver (hepatitis/hepatic dysfunction),
- kidney failure (renal impairment or failure), lack of oxygen to the kidneys (renal papillary or tubular necrosis), with symptoms such as passing less urine, short breath, nausea, tiredness, swelling in your legs or ankles,
- shortness of breath or troubled breathing (dyspnoea),
- worsening of asthma or tightening of air passages which causes difficulty breathing, coughing, wheezing and chest tightness (bronchospasm),
- lack of blood flow to parts of your body causing a stroke (haemorrhagic stroke, ischaemic stroke).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness,
- stomach cramps, pain or discomfort in the stomach area, pain in the upper stomach area (epigastric pain or discomfort), heartburn, nausea, dry mouth,
- vomiting, passing wind (flatulence), loose stools (diarrhoea), difficulty passing stools (constipation),
- skin rash,
- nervousness, restlessness, inability to fall asleep (insomnia).

Less frequent side effects:

- Disturbed sense of reality (psychotic reactions), feeling extremely sad (depression),
- headache, nervousness or irritability, confusion, seeing or hearing things that are not really there (hallucinations), agitation, tiredness,
- a disorder of the nerves which can cause weakness, tingling or numbness (peripheral neuropathy), feeling sleepy (drowsiness), trouble in sleeping,
- blurred or double vision or change in vision, swelling in the eye (conjunctivitis), dry, irritated or swollen eyes,
- ringing or buzzing in ears, lessened or changes in the way you hear,
- swelling due to fluid collecting in the body (oedema), high blood pressure (hypertension), unexplained nose bleeds, reddening of the face or neck (flushing),
- loss of appetite, upset stomach (indigestion), swelling in the stomach (gastritis), blood in stools (melaena), vomiting blood (haematemesis), irritation, soreness of mouth, sores in the mouth (gingival ulceration or aphthous stomatitis, ulcerative stomatitis),
- swelling or inflammation of the small intestine (colitis and Crohn's disease, swelling of the food pipe (oesophagitis), narrowing of the intestine which shows symptom such as nausea or stomach pain (intestinal diaphragm-like stricture),
- hair loss (alopecia),
- unexplained vaginal bleeding, blood in urine, bladder infection (cystitis), passing a large amount of urine (polyuria),
- sense of whirling or dizziness (giddiness), sweating, muscle weakness, involuntary muscle movements (tremor),
- ringing in the ears (tinnitus),
- difficult or painful urination.

Side effects with an unknown frequency:

- Mood or mental changes,
- swelling or inflammation of the small intestine (enterocolitis),
- abnormal results in liver function tests,
- kidney stones (renal calculi or ureteral obstruction),
- changes in the way your body processes food (altered metabolism, changes in your blood sugar levels (disturbances of glucose metabolism),
- feeling worried (anxiety), abnormal behaviour, unrealistic feeling of well-being (euphoria),
- fear, feeling sleepy (somnolence),
- thirst,
- difficulty or pain when passing urine (micturition, dysuria).

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 and to

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of DECLOZIT.

5. How to store DECLOZIT

Store all medicines out of reach of children.

Store at or below 25 °C, protected from light and air.

Keep blister in carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 DECLOZIT contains

The active substances are 200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, hypromellose, lactose monohydrate, maize starch, microcrystalline cellulose, pregelatinised maize starch, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin, red iron oxide, yellow iron oxide.

Contains sugar: Lactose monohydrate 6,7 mg

What DECLOZIT looks like and contents of the pack

DECLOZIT is a brown to light brown colour, modified capsule shape, biconvex film-coated tablet.

12 or 24 tablets are packed in clear PVC/PVdC/silver aluminium foil blister strips, or clear PVC/Aclar/silver aluminium foil blister strips. Each blister strip contains 12 tablets. Blister strips are packed in an outer cardboard carton.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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