

## **PROPOSED PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

S4

#### **DUROBAC (TABLETS)**

80 mg Trimethoprim and 400 mg Sulphamethoxazole.

#### **DUROBAC DOUBLE STRENGTH (TABLETS)**

160 mg Trimethoprim and 800 mg Sulphamethoxazole.

**Sugar free**

**Contains preservative: Nipastat**

**Read all of this leaflet carefully before you start taking DUROBAC.**

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- **DUROBAC** 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.

Date of PI: 29/01/2024  
Approved PIL



## **What is in this leaflet**

1. What **DUROBAC** is and what it is used for
2. What you need to know before you take **DUROBAC**
3. How to take **DUROBAC**
4. Possible side effects
- 5 How to store **DUROBAC**
6. Contents of the pack and other information

### **1. What DUROBAC is and what is it used for:**

**DUROBAC and DUROBAC DS** contains two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. As **DUROBAC** only works against some types of bacteria, it is only suitable for treating some types of infections.

It can be used to treat:

- Upper and lower lung infections
- Urinary bladder or urinary tract infections
- Gastrointestinal tract (your mouth, oesophagus (gullet), stomach and intestines) infections
- Genital tract (reproductive track including sexually transferred diseases) infections.

Date of PI: 29/01/2024  
Approved PIL



- Skin infections
- Other infections caused by bacteria that **DUROBAC** works against

## **2. What you need to know before you take DUROBAC:**

### **Do not take DUROBAC if :**

- You are allergic (hypersensitive) to sulfamethoxazole, trimethoprim, sulfonamides or any of the other ingredients in **DUROBAC** (listed in section 6).
- you have been told that you have porphyria.
- you have severe liver or severe kidney problems.
- you have been told that you have an anaemia due to not having enough folic acid.
- you are pregnant or breastfeeding.

## **Warnings and precautions**

### **Take special care with DUROBAC if you:**

- are suffering from AIDS or are having special treatment that lowers your immune system, e.g. after an organ transplant. You can experience more severe side-effects.
- have skin rashes, often accompanied by flu-like symptoms after taking **DUROBAC**. The rash may progress to widespread blistering or peeling of the

skin. This can be a serious skin reaction to **DUROBAC**. Stop taking **DUROBAC** and seek urgent advice from your doctor.

- don't have enough folic acid (a vitamin) in your body, which can make your skin pale and make you feel tired, weak and breathless. Your doctor might prescribe additional folic acid with your **DUROBAC** treatment.
- are elderly you may have more severe side effects, e.g. problem with your blood causing bruises or bleeding (thrombocytopenia). This can happen more frequently if you are also taking water tablets, e.g. thiazides.
- have kidney problems, your doctor might reduce the **DUROBAC** dosage (see section 3). You should take enough fluids , especially if you are on high dosages of **DUROBAC**.
- are allergic to sulfonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You might be allergic to **DUROBAC** as well.

#### **Other medicines and DUROBAC:**

**Always tell your healthcare professional if you or your child are taking any other medicine. (This includes complementary or traditional medicines).**

Tell your doctor if you are taking any of the following medicines medicine (this includes complementary or traditional medicines.):

Date of PI: 29/01/2024  
Approved PIL



- are taking any of the following, as the effect of these medicines can become stronger and your doctor might monitor you more closely or need to change your treatment:
  - Warfarin or other medicines to thin your blood.
  - Methotrexate, used to treat certain cancers or certain diseases affecting your immune system.
  - Phenytoin, used to treat epilepsy.
  - Sulfonylurea compounds, used to treat diabetes.
  - Digoxin or procainamide to treat problems with the way your heart beats.
  - Tolbutamide and repaglinide used to treat diabetes.
- Para-aminobenzoic acid (PABA) is a supplement and can increase your risk of side effects, e.g. crystals forming in your urine.
- Cyclosporin, used in e.g. kidney transplant, as it can cause your kidneys to work less effectively.
- Pyrimethamine used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g. anaemia.
- Zidovudine used in the treatment of HIV, as it can increase your risk of developing less blood cells.
- Lamivudine used in the treatment of HIV, as **DUROBAC** at high dosages can increase the effect of lamivudine.

Date of PI: 29/01/2024

Approved PIL



- Medicines that can increase the amount of potassium in your blood, such as diuretics (water tablets, which help increase the amount of urine you produce, such as spironolactone), steroids (like prednisolone) and digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems). These medicines can increase the amount of potassium to dangerously high levels in your blood.
- Folic acid, a supplement can lower the effect of **DUROBAC**.
- Contraceptives can become less effective when taking with **DUROBAC**. You should use additional protection while on **DUROBAC** treatment.
- Azathioprine used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease. Your doctor might monitor your blood cells more closely.

#### **DUROBAC with food, drink, and alcohol:**

The tablets should be swallowed with a glass of water and food.

Drink plenty of fluid such as water while you are taking **DUROBAC**.

#### **Pregnancy and breastfeeding and fertility:**

The safety in pregnancy and lactation has not been established.

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 professional for advice before taking **DUROBAC**.

Date of PI: 29/01/2024  
Approved PIL



You should not take **DUROBAC** while you are pregnant or breastfeeding your baby.

### **Driving and using machines:**

It is not always possible to predict to what extent **DUROBAC** 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 **DUROBAC** affects them.

### **DUROBAC contains Nipastat**

**DUROBAC** contains Nipastat, a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed).

### **3. How to take DUROBAC:**

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

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

It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.

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

### **The usual dose is:**

### **DUROBAC**

### **Adults and children over 12 years:**

Date of PI: 29/01/2024  
Approved PIL



- Two tablets every 12 hours after meals.
- The maximum dose (for particularly severe cases) is three **DUROBAC** tablets every 12 hours.
- The minimum dosage for long term treatment is one **DUROBAC** tablet every 12 hours.

## **DUROBAC D/S**

### **Adults and children over 12 years:**

- One tablet every 12 hours after meals.
- The maximum dose (for particularly severe cases) is one and a half **DUROBAC D/S** tablets every 12 hours.
- The minimum dosage for long term treatment (more than 14 days) is half a **DUROBAC D/S** tablet every 12 hours.

### **Renal Impairment**

Your doctor will do a blood test and calculate your dosage depending on the results.

No Information is available for children with renal failure.

### **If you take more DUROBAC than you should:**

When taken more **DUROBAC** than you/they should, you may feel nausea, vomit, dizzy and confused. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Date of PI: 29/01/2024

Approved PIL



## **If you forget to take a dose of DUROBAC:**

Try to take **DUROBAC** as prescribed by your healthcare professional. However, if you miss a dose, do not take a double dose to make up for forgotten individual doses.

### **4. Possible side effects**

**DUROBAC** can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching)
- Severe blistering of the skin, pain and pruritus (itchy skin). These serious skin reactions includes toxic epidermal necrolysis (Lyell's syndrome), Steven-Johnson syndrome (SJS), systemic lupus erythematosus and "Fixed Drug Eruptions" to name a few (see also section 2).
- Unexpected worsening of cough and shortness of breath.
- Increase in liver enzymes (blood tests) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite,

feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

- Sudden headache or stiffness of your neck, accompanied by fever. This can be aseptic meningitis.

These are all very serious side effects. If you have them, you may have had a serious reaction to **DUROBAC**. You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following:**

### **Sulfamethoxazole**

#### **Frequent side effects:**

- A fungal infection called thrush or candidiasis which can affect the mouth or vagina
- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).
- Headache
- Nausea
- Diarrhoea
- Rash

#### **Less frequent side effects:**

Date of PI: 29/01/2024  
Approved PIL



- Pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools)
- Changes in the blood cells, resulting in feeling weak, tired or listless, pale skin, and more frequent infections
- Hypothyroidism where the thyroid doesn't create and release enough thyroid hormone into your bloodstream. This makes you feel tired, gain weight and unable to tolerate cold temperatures.
- Low blood sugar
- Low sodium concentration in your blood
- Decreased appetite
- Build-up of acid in your body (metabolic acidosis)
- Depression
- Seeing strange or unusual sights (hallucination)
- Psychotic disorder (a mental state in which you may lose balance and coordination (ataxia))
- Dizziness
- Feeling tired
- Difficulty to sleep
- Tingling or numbness in your hands and feet
- Seizures
- Vision disorders, seeing flickering or flashing lights

Date of PI: 29/01/2024  
Approved PIL



- Sort-sighted for a short period
- Inflammation of the eye which causes pain and redness
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)
- Vomiting
- Swollen and inflamed tongue
- Inflamed and sore mouth (touch with reality)
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (Pancreatitis)
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Arthralgia (pains in the joints)
- Myalgia (pains in the muscles)
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual.
- Blood or cloudiness in your urine
- Kidney problems

### **Trimethoprim**

#### **Frequent side effects**

- Headache

Date of PI: 29/01/2024

Approved PIL



- Itchy skin
- Rash
- Fever,
- Nausea
- Vomiting
- Sore mouth

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

### **Reporting of side effects**

If you get side effects, talk to your doctor or 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>. By reporting side effects, you can help provide more information on the safety of **DUROBAC**.

### **5. How to store DUROBAC**

#### **STORE ALL MEDICINE OUT OF REACH OF CHILDREN**

- Store **DUROBAC** at or below 25 °C in original container. Protect from light and moisture.
- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.

Date of PI: 29/01/2024  
Approved PIL



- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

## **6. Contents of the pack and other information**

### **What DUROBAC contains:**

**The active substance are:** trimethoprim and sulfamethoxazole

**The other ingredients are:** Hydrogenated vegetable oil, magnesium stearate, nipastat, pregelatinized starch maize, purified water, sodium carboxymethyl starch, starch maize.

### **What DUROBAC looks like and contents of the pack**

**DUROBAC:** Flat, white bisected tablets with bevelled edges.

**DUROBAC DOUBLE STRENGTH:** White, oblong, biconvex, bisected tablets.

**DUROBAC:** 28 or 56 tablets packed in a L.D.P.E “ziploc” plastic patient ready packs and 100, 500 or 1000 tablets packed in HDPE containers.

**DUROBAC D/S:** 30 or 100 tablets packed in white securitainers and 1000 tablets packed in HDPE containers.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

Innovata Pharmaceuticals Pty Ltd

Date of PI: 29/01/2024

Approved PIL



*Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd  
Product Proprietary Name: DUROBAC AND DUROBAC D/S  
Dosage Form & Strength: tablet, 80 mg Trimethoprim and 400 mg Sulphamethoxazole and 160 mg Trimethoprim and 800 mg Sulphamethoxazole.*

*CTD, Module 1*

Crownwood Office Park

100 Northern Parkway

Building D

Ormonde

Johannesburg

2091

**This leaflet was revised in**

*Date of first authorization*

November 1993

*Date of revision of text*

29/01/2024

**Registration number**

**DUROBAC:** J/20.2/279

**DUROBAC DOUBLE STRENGTH:** P/20.2/55

**Access to the corresponding Professional information:**

Follow the link for the corresponding Professional Information for **DUROBAC** and

**DUROBAC D/S:**

[pi-pil-repository.innovata.co.za](http://pi-pil-repository.innovata.co.za),

Date of PI: 29/01/2024

Approved PIL



*Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd  
Product Proprietary Name: DUROBAC AND DUROBAC D/S  
Dosage Form & Strength: tablet, 80 mg Trimethoprim and 400 mg Sulphamethoxazole and 160 mg Trimethoprim and 800 mg Sulphamethoxazole.*

*CTD, Module 1*

**alternatively please scan the QR code below:**



Date of PI: 29/01/2024  
Approved PIL

A handwritten signature in black ink, appearing to be 'Rhu' or similar, written over a circular scribble.

## **PASIËNT INLIGTINGBILJET**

### **SKEDULERINGSTATUS**

S4

### **DUROBAC (TABLETTE)**

80 mg Trimetoprim en 400 mg Sufametoksasool.

### **DUROBAC DOUBLE STRENGTH (TABLETTE)**

160 mg Trimetoprim en 800 mg Sulfametoksasool.

### **Suikervry**

**Bevat preserveermiddel: Nipastat**

**Lees die volledige biljet noukeurig deur voordat u begin om DUROBAC te neem.**

- Hou hierdie biljet. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- **DUROBAC** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit kan hulle kwaad aandoen, selfs indien hulle simptome dieselfde is as diè wat u het.

Date of PI: 29/01/2024  
Approved PIL



## **Wat is in hierdie biljet**

1. Wat **DUROBAC** is en waarvoor dit gebruik word
2. Wat u behoort te weet voordat u **DUROBAC** neem
3. Hoe om **DUROBAC** te neem
4. Moontlike newe-effekte
5. Hoe om **DUROBAC** te berg
6. Inhoud van die pakkie en ander inligting

### **1. Wat is DUROBAC en waarvoor dit gebruik word:**

**DUROBAC en DUROBAC DS** bevat twee verskillende antibiotika wat genoem word sulfametoksasool en trimetoprim en word gebruik om infeksies te behandel wat veroorsaak word deur sekere bakterieë. Omdat **DUROBAC** slegs werk teen sommige tipes van bakterieë, is dit alleenlik geskik vir behandeling van sommige tipes van infeksies.

Dit kan gebruik word vir behandeling van:

- Boonste en onderste infeksies.
- Urinêre blaas- of urienweg-infeksies.
- Gastroïntestinale kanaal (u mond, esofagus (slukderm), maag en ingewande) infeksies.

Date of PI: 29/01/2024

Approved PIL



- Genitale kanaal (reproduktiewe kanaal, insluitend seksueel oordragbare siektes) infeksies.
- Velinfeksies.
- Ander infeksies veroorsaak deur bakterieë waarteen **DUROBAC** werk

## **2. Wat u behoort te weet voordat u DUROBAC neem:**

### **Moenie DUROBAC neem indien:**

- u allergies is vir sulfametoksasool, trimetoprom, sulfonamiedes of enige van die ander bestanddele in **DUROBAC** nie (aangedui in afdeling 6).
- u ingelig is dat u porfirie het nie.
- u ernstige lewer- of ernstige nierprobleme het nie.
- u ingelig is dat u anemies is, omdat u nie genoeg foliensuur het nie.
- u swanger is of borsvoed nie.

## **Waarskuwings en voorsorgmaatreëls**

### **Neem spesiale sorg met DUROBAC indien u:**

- VIGS het of indien u spesiale behandeling ontvang wat u immuunstelsel verswak, bv. na 'n orgaan-oorplanting. U kan meer ernstige newe-effekte ondervind.
- veluitslag het, dikwels vergesel deur griepagtige simptome na die gebruik van **DUROBAC**. Die uitslag kan voortgaan tot wydverspreide blasievorming of afdop van die vel. Hierdie kan 'n baie ernstige vel-reaksie wees tot

Date of PI: 29/01/2024  
Approved PIL



**DUROBAC.** Staak die gebruik van **DUROBAC** en kry dringende advies van u dokter.

- u nie genoeg foliensuur ('n vitamien) in u liggaam het nie, wat kan veroorsaak dat u vel bleek is en u kan moeg voel, swak en uitasem. U dokter kan addisionele foliensuur voorskryf met u **DUROBAC**-behandeling.
- u bejaard is kan u meer ernstige newe-effekte hê, bv. probleme met u bloed wat veroorsaak dat u kneus of bloei (trombositopenie). Dit kan meer dikwels gebeur indien u ook water tablette neem, bv. tiasiede.
- u probleme met u niere het, kan u dokter die **DUROBAC** dosering verminder (sien afdeling 3). U moet genoeg vloeistof inneem, veral indien u op hoë **DUROBAC**-dosering is.
- u allergies is vir sulfonamiede. Voorbeelde sluit in sulfonielureum (soos glikasied en glibenklamied) of asetosolamied en tiasied diuretiese middels (water tablette). U kan ook allergies wees vir **DUROBAC**.

#### **Ander medisyne en DUROBAC:**

**Vertel altyd u gesondheidsorgpersoon indien u of u kind enige ander medisyne neem. (Dit sluit in alle komplementere of tradisionele medisyne.)**

Vertel u dokter indien u enige van die volgende medisyne neem (dit sluit in komplementere of tradisionele medisyne.):

Date of PI: 29/01/2024  
Approved PIL



- indien u enige van die volgende neem, omdat die effek van hierdie medisyne sterker kan word en u dokter moet u maandeliks versigtig monitor of u behandeling verander:
  - Warfarien of ander medisyne om u bloed dun te maak.
  - Metotreksaat, word gebruik om sekere kanker of sekere siektes te behandel wat u immuunstelsel beïnvloed.
  - Fenitoïen, word gebruik om epilepsie te behandel.
  - Sulfonielureum samestellings, word gebruik om diabetes te behandel.
  - Digoksien of prokaïenamied, om probleme te behandel van die manier waarop u hart klop.
  - Tolbutamied en repaglinied, wat gebruik word om diabetes te behandel.
- Para-aminobensoë-suur (PABA) is 'n aanvulling en kan u risiko vir nuwe-effekte verhoog, bv. kristalvorming in u urine.
- Siklosporien, wat gebruik word in bv. nieroorplanting, omdat dit kan veroorsaak dat u niere minder effektief werk.
- Pirimetamien, wat gebruik word vir die behandeling en voorkoming van malaria en om diarree te behandel, omdat u nuwe-effekte kan ontwikkel, bv. anemie.
- Sidovudien, wat gebruik word vir die behandeling van MIV, omdat dit die risiko vir ontwikkeling van minder bloedselle kan verhoog.

- Lamivudien, wat gebruik word by die behandeling van MIV, omdat **DUROBAC** by hoë doserings die effek van lamivudien kan laat toeneem.
- Medisynes wat die hoeveelheid kalium in u bloed kan laat toeneem, soos diuretika (water tablette, wat kan help om die hoeveelheid urine wat u produseer te laat toeneem, soos spironolaktoon), steroïede (soos prednisoloon) en digoksien of AOE-inhibeerders (kan gebruik word by die behandeling van hoë bloeddruk of sommige hartprobleme). Hierdie medisynes kan die hoeveelheid kalium tot gevaarlike vlakke laat toeneem in u bloed.
- Foliniese suur, 'n aanvulling wat die effek van **DUROBAC** kan laat afneem.
- Kontraseptiewe middels kan minder effektief wees wanneer **DUROBAC** geneem word. U moet addisionele beskerming gebruik terwyl u op **DUROBAC**-behandeling is.
- Asatioprien wat gebruik word by pasiënte na orgaan-oorplanting of om immuunstelselafwykings of inflammatoriese ingewand-siektes te behandel. U dokter mag u bloedselle meer omsigtig monitor.

### **DUROBAC met voedsel, drankies en alkohol:**

Die tablette moet ingesluk word met 'n glas water en voedsel.

Drink baie vloeistof, soos water, terwyl u **DUROBAC** gebruik.

### **Swangerskap en borsvoeding en fertiliteit:**

Die veiligheid gedurende swangerskap en laktasie is nog nie vasgestel nie.

Indien u swanger is of borsvoed, dink dat u swanger kan wees of 'n baba beplan,

Date of PI: 29/01/2024

Approved PIL



raadpleeg asseblief u dokter, apteker of ander gesondheidsorgpersoon vir advies voordat u **DUROBAC** neem.

U moet nie **DUROBAC** gebruik terwyl u swanger is of u baba borsvoed nie.

### **Bestuur en gebruik van masjinerie:**

Dit is nie altyd moontlik om te voorspel tot watter mate **DUROBAC** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie aan boonste aktiwiteite deelneem nie, totdat hulle bewus is tot watter mate

**PUROBAC** hulle beïnvloed.

### **DUROBAC bevat Nipastat**

**DUROBAC** bevat Nipastat, 'n mengsel van parahidroksibensoaat esters. Dit kan allergiese reaksies veroorsaak (moontlik vertraagde).

### **3. Hoe om DUROBAC te neem:**

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

Neem hierdie medisyne altyd presies soos u dokter aanbeveel het. U moet u dokter of apteker raadpleeg indien u nie seker is nie.

Dit is belangrik om die volledige kursus van behandeling te voltooi. Die tydperk van die kursus sal afhang van u behoefte en die siekte wat behandel word.

Indien u die indruk het dat die effek van **DUROBAC** te sterk of te swak is, vertel u dokter of apteker.

### **Die gewone dosis is:**

### **DUROBAC**

Date of PI: 29/01/2024  
Approved PIL



### **Volwassenes en kinders ouer as 12 jaar:**

- Twee tablette elke 12 uur na maaltye.
- Die maksimum dosis (vir veral ernstige gevalle) is drie **DUROBAC** tablette elke 12 uur.
- Die minimum dosering vir langtermyn behandeling is een **DUROBAC** tablet elke 12 uur.

### **DUROBAC D/S**

#### **Volwassenes en kinders oor 12 jaar oud:**

- Een tablet elke 12 uur na maaltye.
- Die maksimum dosis (by veral ernstige gevalle) is een en 'n halwe **DUROBAC D/S** tablet elke 12 uur.
- Die minimum dosering vir langtermyn behandeling (meer as 14 dae) is 'n halwe **DUROBAC D/S** tablet elke 12 uur.

### **Renale Inkorting**

U dokter sal bloedtoetse doen en u dosering sal bereken word afhangende van die resultate.

Geen inligting is beskikbaar vir kinders met nierversaking nie.

### **Indien u meer DUROBAC geneem het as wat u moes:**

Wanneer u meer **DUROBAC** geneem het as wat u moes, kan u naar voel, braak, duiseligheid en verwarring ondervind. Ingeval van oordosering, raadpleeg u dokter of apteker. Indien albei nie beskikbaar is nie, kontak die naaste hospitaal of

Date of PI: 29/01/2024

Approved PIL



vergiftingsentrum.

**Indien u vergeet het om 'n dosis DUROBAC te neem:**

Probeer om **DUROBAC** te neem soos voorgeskryf deur u gesondheidsorgpersoon.

Indien u egter 'n dosis mis, moenie 'n dubbele dosis neem om op te maak vir die individuele doserings wat u vergeet het nie.

**4. Moontlike newe-effekte**

**DUROBAC** kan newe-effekte hê.

Nie alle newe-effekte gerapporteer vir hierdie medisyne is ingesluit in hierdie biljet nie. Indien u algemene gesondheid agteruitgaan terwyl u hierdie medisyne neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgpersoon vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **DUROBAC** en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal:

- Allergiese reaksie (bv. opswel in die mond, tong, gesig en keel, jeuk)
- Ernstige afskilfering van die vel, pyn en pruritus (jeukerige vel). Hierdie ernstige vel-reaksies sluit in toksiese epidermale nekrolise (Lyell se sindroom), Steven-Johnson se sindroom (SJS), sistemiese lupus erythematosus en "Vaste Middel Erupsies" om slegs 'n paar te meld (sien ook afdeling 2).
- Onverwagte agteruitgang van hoës en asemtekort.
- Toename in lewerensieme (bloedtoetse) en inflammasie van die lewer, soms met geelsug (lewersiekte met naarheid, braking, verlies van apyt, algemene

Date of PI: 29/01/2024  
Approved PIL



gevoel van ongesond voel, koors, jeuk, geel word van die vel en oë, en donker gekleurde uriene.

- Skielike hoofpyn of styfheid van u nek, vergesel deur koors. Dit kan aseptiese meningitis wees.

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, het u 'n ernstige reaksie gehad met **DUROBAC**. U kan moontlik dringende mediese sorg of hospitalisering benodig.

**Vertel u dokter indien u enige van die volgende opmerk:**

### **Sulfametoksasool**

#### **Dikwelse newe-effekte:**

- 'n Fungus-infeksie wat genoem word sproei of kandidiase, wat in die mond of vagina kan voorkom
- Hoë vlakke van kalium in u bloed, wat abnormale hartklop (palpitاسies) kan veroorsaak)
- Hoofpyn
- Naarheid
- Diarree
- Uitslag

#### **Minder dikwelse newe-effekte:**

- Pseudomembraneuse kolitis (infeksie van die kolon met gevolglike waterige en soms bloederige stoelgang)

Date of PI: 29/01/2024  
Approved PIL



- Veranderinge in die bloedselle, met gevolglike gevoel van swakheid, moegheid of lusteloosheid, bleek vel en meer dikwels infeksies
- Hipotiroïedisme waar die tiroïed nie genoeg tiroïedhormoon maak en vrystel in u bloedstroom nie. Dit veroorsaak dat u moeg voel, gewig aansit en nie koue temperature kan hanteer nie.
- Lae bloedsuiker
- Lae natriumkonsentrasie in u bloed
- Afname in aptyt
- Opbou van suur in u liggaam (metaboliese asidose)
- Depressie
- Die sien van snaakse of ongewone sigte (hallusinasie)
- Psigotiese afwyking ('n geestestoestand waar u verlies van balans of koördinasie kan verloor (ataksie)
- Duiseligheid
- Gevoel van moegheid
- Probleme om te slaap
- Tinteling of gevoelloosheid in u hande en voete
- Siekte-aanvalle
- Gesigsafwykings, flikkerende sig of flitsende ligte
- Kortsigtigheid vir 'n kort tydperk
- Inflammasie van die oë wat pyn en rooiheid kan veroorsaak

Date of PI: 29/01/2024

Approved PIL



- Gevoel van onstabiliteit of dronkerigheid
- Lui of ander ongewone klanke in u ore
- Sianose (blouerige of gryserige kleur van die vel, naels, lippe of om die oë).
- Braking
- Opgeswelde en ontsteekte tong
- Ontsteekte en seer mond nflamed and sore mouthse touch with reality)
- Inflammasie van die pankreas met ernstige boonste maagpyn, dikwels met naarheid en braking (pankreatitis)
- Die voorkoms van 'n uitslag of sonbrand wanneer u buite gewees het (selfs op 'n bewolkte dag)
- Artralgie (pyn in die gewrigte)
- Mialgie (pyn in die spiere)
- Probleme met u uriene. Probleme om te urineer. Meer of minder urineer as gewoonlik.
- Bloed of wolkerigheid in u uriene
- Nierprobleme

### **Trimetoprim**

#### **Dikwelse neue-effekte**

- Hoofpyn
- Jeukerige vel
- Uitslag

Date of PI: 29/01/2024  
Approved PIL



- Koors
- Naarheid
- Braking
- Seer mond

Indien u enige newe-effekte opmerk wat nie gemeld is in hierdie biljet nie, stel asseblief u dokter in kennis daarvan.

### **Rapporteer van newe-effekte**

Indien u newe-effekte ontwikkel, raadpleeg u dokter of apteker of verpleegkundige.

U kan ook newe-effekte rapporteer aan SAHPRA via die “**6.04 Adverse Drug Reactions Reporting Form**”, wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>.

Deur newe-effekte te rapporteer kan u help om meer inligting te voorsien omtrent die veiligheid van **DUROBAC**.

### **5. Hoe om DUROBAC te berg**

#### **BERG ALLE MEDISYNES BUIE DIE BEREIK VAN KINDERS**

- Berg **DUROBAC** by of benede 25 °C in oorspronklike houer. Beskerm teen lig en vog.
- Moenie hierdie medisyne gebruik na die vervaldatum wat gewys word op die pakkie nie.

Date of PI: 29/01/2024  
Approved PIL



- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie van u ongebruikte medisyne ontslae raak deur dit in afvoerpype of die rioolsisteme te gooi nie (bv. toilette).

## **6. Inhoud van die pakkie en ander inligting**

### **Wat DUROBAC bevat:**

**Die aktiewe substansie is:** trimetoprim en sulfametoksasool

**Die ander bestanddele is:** Gehidrogeneerde groente olie, magnesiumstearaat, nipastat, gepregelatiniseerde mieliestysel, gesuiwerde water, natrium karboksimeetielstysel, mieliestysel.

### **Hoe DUROBAC lyk en inhoud van die pakkie**

**DUROBAC:** Plat, wit, gedeelde tablette met afgeskuinste kante.

**DUROBAC DOUBLE STRENGTH:** Wit, langwerpige, bikonvekse, gedeelde tablette.

**DUROBAC:** 28 of 56 tablette verpak in L.D.P.E "ziploc" plastiese pasiënt-gereed pakkies en 100, 500 of 1000 tablette verpak in HDPE houers.

**DUROBAC D/S:** 30 of 100 tablette verpak in wit securitainers en 1000 tablette verpak in HDPE houers.

Nie alle pakgroottes sal bemark word nie.

### **Houer van Sertifikaat van Registrasie**

Innovata Pharmaceuticals Pty Ltd

Crownwood Office Park

100 Northern Parkway

Building D

Date of PI: 29/01/2024

Approved PIL



*Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd  
Product Proprietary Name: DUROBAC AND DUROBAC D/S AFR  
Dosage Form & Strength: tablet, 80 mg Trimethoprim and 400 mg Sulphamethoxazole and 160 mg Trimethoprim and 800 mg Sulphamethoxazole.*

*CTD, Module 1*

Ormonde

Johannesburg

2091

**Hierdie biljet was verander in**

*Datum van eerste goedkeuring*

November 1993

*Datum van revisie van teks*

29/01/2024

**Registrasienuommer**

**DUROBAC:** J/20.2/279

**DUROBAC DOUBLE STRENGTH:** P/20.2/55

**Toegang tot die ooreenstemmende Professionele Inligting:**

Volg die link vir die ooreenstemmende Professionele Inligting vir **DUROBAC** en

**DUROBAC D/S:**

[pi-pil-repository.innovata.co.za](http://pi-pil-repository.innovata.co.za),

alternatiewelik skandeer asseblief die QR kode hieronder:



Date of PI: 29/01/2024

Approved PIL

