

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S4**BACTRIM, 80 mg/400 mg per 5 mL, solution for infusion****Trimethoprim and Sulfamethoxazole****Sugar free****Read all of this leaflet carefully before BACTRIM is administered.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What BACTRIM is and what it is used for
2. What you need to know before BACTRIM is administered
3. How BACTRIM will be administered
4. Possible side effects
5. How to store BACTRIM
6. Contents of the pack and other information.

1. What BACTRIM is and what it is used for

BACTRIM treats and prevents a type of lung infection (*Pneumocystis jirovecii* pneumonia) in adults and children, particularly in patients with a severely low immune system.

BACTRIM is also used to treat a disease called toxoplasmosis; the parasite is often found in cat faeces (soil) and undercooked meat.

2. What you need to know before BACTRIM is administered**BACTRIM should not be administered**

- If you are hypersensitive (allergic) to BACTRIM, sulfamethoxazole, trimethoprim, any other sulfonamide, or any of the other ingredients of BACTRIM (listed in section 6).
- If you have severe liver or kidney disease, any blood disorder or megaloblastic anaemia.
- If it is for a child who is prematurely or newly born or in the first 6 weeks of life.
- If you have vitamin B₁₂ or folic acid deficiencies.
- If you are pregnant and breastfeeding.
- If you have porphyria (a group of disorders that result from a build-up of natural chemicals that produce porphyrin in your body).
- If you are taking dofetilide (used to treat heart rhythm disorders).

Warnings and precautions

Take special care with BACTRIM

- If you have a serious adverse reaction such as:
 - Blood dyscrasias is a blood disorder with symptoms such as fast heartbeat, shortness of breath, fainting, tiredness and pale skin
 - Stevens-Johnson syndrome or toxic epidermal necrolysis with symptoms such as a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals
 - Drug reaction with eosinophilia and systemic symptoms (DRESS) consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes)
 - Liver failure with symptoms such as nausea, weakness, fatigue and abdominal pain.
- If you have a history of severe allergy and bronchial asthma with symptoms such as shortness of breath, chest pain, coughing and wheezing.
- If you have kidney problems.
- If you are elderly.
- If you have thyroid problems.

Other medicines and BACTRIM

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

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

- Dofetilide, amiodarone (used to treat heart rhythm disorders).
- Amantidine (used to treat Parkinson's disease).
- Memantadine (used to treat Alzheimer's disease).
- Lamuvidine (used to treat hepatitis B).
- Paclitaxel, mercaptopurine (used to treat certain types of cancer).
- Dapsone (used to treat leprosy).
- Repaglinide, rosiglitazone, pioglitazone, glibenclamide, gliclazide, glipizide, chlorpropamide, tolbutamide (used to treat high blood sugar levels).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Warfarin (used to thin your blood and prevent blood clots from forming).
- Phenytoin (used to treat epilepsy).
- Nucleoside analogues (used to treat viral infections such as hepatitis B and C and human immunodeficiency virus (HIV)).
- Tacrolimus (used to prevent organ rejection after a transplant).
- Azathioprine (used to treat inflammatory conditions such as rheumatoid arthritis (inflammation in the joints)).
- Clozapine (used to treat mood or mental disorders).
- Diuretic medicines (assist your body to get rid of extra water and salt).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Methotrexate (used to treat cancer, rheumatoid arthritis).
- Pyrimethamine (used to treat malaria).
- Antihypertensive medicines (used to treat high blood pressure).
- Prednisolone (used to treat inflammation).

BACTRIM with alcohol

The amount of alcohol in BACTRIM may alter the effects of other medicines. Talk to your doctor if you are taking other medicines.

If you are addicted to alcohol, talk to your doctor before BACTRIM is administered.

Pregnancy, breastfeeding and fertility

BACTRIM should not be administered if you are pregnant or breastfeeding as safety and efficacy have 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 health care provider for advice before BACTRIM is administered.

Driving and using machines

The amount of alcohol in BACTRIM can affect your ability to drive a vehicle or use machines because it may affect your judgement and how fast you react (see BACTRIM contains ethanol).

It is not always possible to predict to what extent BACTRIM may interfere with your daily activities. BACTRIM can cause hallucinations (seeing or hearing things that do not exist) (see section 4). You should ensure that you do not engage in the above activities until you are aware of the measure to which BACTRIM affects you.

BACTRIM contains ethanol, propylene glycol and sodium

BACTRIM contains 500 mg of alcohol (ethanol) in each 5 mL ampoule which is equivalent to 10 % *m/v*. The amount in 5 mL of BACTRIM corresponds to 13 mL beer or 6 mL wine.

The alcohol in BACTRIM is likely to affect young children. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities. If you have epilepsy, liver problems, are pregnant or breastfeeding talk to your doctor before BACTRIM is administered.

BACTRIM contains 2 050 mg propylene glycol per 5 mL ampoule, corresponding to 410 mg/mL. If

your child is less than 5 years old, contact your doctor or pharmacist before BACTRIM is administered, especially if your child is also receiving other medicines containing propylene glycol or alcohol. If you are pregnant or breastfeeding, have liver or kidney disease do not receive BACTRIM unless recommended by your doctor. Your doctor may carry out additional checks when BACTRIM is administered.

BACTRIM contains 34 mg of sodium (a major component of common salt/table salt) per ampoule. This is equivalent to 1,7 % of the recommended maximum daily intake of sodium for an adult.

3. How BACTRIM will be administered

You will not be expected to administer BACTRIM to yourself. It will be administered to you by a person who is qualified to do so. Your doctor will determine the dose for you or your child and the length of treatment.

If you have the impression that the effect of BACTRIM is too strong or too weak, talk to your doctor or pharmacist.

If more BACTRIM is administered to you than should be

Since a health care provider will administer BACTRIM, he/she will control the dosage. However, in the event of overdosage your health care provider will manage the overdosage.

4. Possible side effects

BACTRIM can have side effects. Not all side effects reported for BACTRIM are included in this leaflet. Should your general health worsen or if you experience any untoward effects after administration of BACTRIM, please consult your health care provider for advice.

If any of the following happens after administration of BACTRIM, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

- Fainting.

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

- Bleeding or bruising more easily than normal.
- Signs of recurrent infections such as fever or sore throat.
- Shortness of breath.
- Changes in the way your heart beats, for example, if you notice it beating faster or irregular.
- Low sugar levels in your blood (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness).
- Meningitis (infection around the brain or spinal cord with fever, headache, stiff neck and extreme sensitivity to bright light).
- Chest pain.
- Too high or too low levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness).
- Too low levels of sodium in your blood (headache, dizziness, confusion, convulsions (fits), coma).
- Yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.
- Painful, blistering or peeling skin rash.
- Passing more or less urine than is normal for you.
- Urgency to pass urine.
- Blood in your urine.

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:

- Nausea (feeling sick), vomiting (being sick).

Less frequent side effects:

- Oral and/or vaginal thrush (white, furry sore tongue and mouth, sore itchy vagina with vaginal discharge).
- Seeing, feeling or hearing things that are not there.
- Numbness and tingling in your feet or hands.
- Clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements.
- Red, painful eyes, blurred vision, decreased vision.
- Vertigo (sensation of spinning or swaying).
- Ringing in your ears.
- Reddish-purple spots on your legs and feet.
- Diarrhoea.
- Swollen tongue or mouth.
- Redness, warmth, pain itching around a vein.
- Temporary paralysis or weakness of muscles.

Side effects with frequency unknown:

- Abdominal pain that radiates to your back.
- Joint pain, pain in a muscle or group of muscles.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to

SAHPRA via the 6.04 Adverse Drug 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 BACTRIM.

5. How to store BACTRIM

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Protect from light.
- Store in the original package.
- Do not use this medicine after the expiry date printed on the outer pack.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BACTRIM contains

BACTRIM contains the active ingredients trimethoprim and sulfamethoxazole, also known as cotrimoxazole.

Each 5 mL solution contains 80 mg trimethoprim and 400 mg sulfamethoxazole.

Contains 10 % *m/v* ethanol.

The other ingredients are ethanol, ethanolamine, propylene glycol, sodium hydroxide and water for injection.

What BACTRIM looks like and contents of the pack

Clear liquid not more than faintly yellow in a 5 mL glass ampoule.

Type 1 flint glass ampoules packed in trays containing 5 ampoules.

Holder of Certificate of Registration

LeBasi Pharmaceuticals (Pty) Ltd

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Bactrim

Solution for infusion

80 mg trimethoprim and 400 mg sulfamethoxazole per 5 mL

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