Bactrim® 400/80

sulfamethoxazole 400 mg/5 mL and trimethoprim 80 mg/5 mL concentrate for solution for infusion

What is in this leaflet

Please read this leaflet carefully before you start using Bactrim® 400/80.

This leaflet answers some common questions about Bactrim® 400/80. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Bactrim® 400/80 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Bactrim® 400/80 is used for

Bactrim® 400/80 is used to treat infections where the oral dosage form of the antibiotic is not appropriate.

Bactrim® 400/80 contains the active ingredients sulfamethoxazole and trimethoprim. Sulfamethoxazole belongs to a group of medicines known as sulfonamides. Trimethoprim belongs to a group of medicines known as benzylpyrimidines. Together, both substances are more efficient than either one alone.

Your doctor may have prescribed Bactrim® 400/80 for another reason.

Ask your doctor if you have any questions about why Bactrim® 400/80 has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Bactrim® 400/80

When you must not use it

Do not use Bactrim® 400/80 if:

- you are allergic to trimethoprim
- you are allergic to sulfamethoxazole or drugs containing ‘sulfa’
- you are allergic to any of the ingredients listed at the end of this leaflet
- you have severe liver disease
- you have abnormal cells in the blood
- you have severe kidney disease
- you have abnormal red blood cells (anaemias) associated with low levels of folic acid
- you have a low platelet count with bleeding or bruising more easily than normal with previous use of trimethoprim and/or sulfonamides
- you are taking Dofetilide, used to treat heart arrhythmias.

Bactrim® 400/80 should not be given to premature babies or newborn babies (up to 8 weeks old).

If you are not sure whether you should start using Bactrim® 400/80, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you have any other medical conditions including
    - a deficiency of the enzyme glucose-a6-phosphate dehydrogenase (G6PD)
    - anaemia or other blood disorders
    - malnutrition
    - rheumatoid arthritis
    - kidney disease, or kidney transplant
    - liver disease (hepatitis)
    - HIV positive or AIDS
    - renal impairment or failure
    - phenylkenonuria
    - porphyria
    - thyroid disease
    - folate deficiency
- take any medicines for any other condition

If you have not told your doctor about any of the above, tell them before you start using Bactrim® 400/80.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section Side Effects.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for

you that you are taking Bactrim® 400/80.

Some medicines may interfere with Bactrim® 400/80. These include:

- Methotrexate
- Medicines that change the acidity of the urine (e.g. salts for cystitis)
- Medicines used to prevent blood clots (blood thinners) such as warfarin
- Phenylbutazone or indomethacin (medicines to reduce inflammation)
- Phenytoin (a medicine for epilepsy)
- Diuretic agents (fluid tablets), particularly thiazides
- Hypoglycaemics (medicines to control blood sugar)
- Digoxin, a medicine used to assist heart function
- Ciclosporin, a medicine used to lower the immune system
- Pyrimethamine, a medicine used in the treatment or prevention of malaria
- Leucovorin (calcium folinate), antithyroid medicines (thionamides) used to treat overactive thyroid
- Antithyroid medicines (thionamides) to treat overactive thyroid
- Tricyclic antidepressants
- Amiodarone used to treat heart arrhythmias
- Paclitaxel a chemotherapy agent
- Dapsone used to treat some skin conditions and leprosy
- Dofetilide used to treat heart arrhythmias
- Amantadine used to treat Parkinson's disease
- Memantine used to treat Alzheimer's disease
- Lamivudine used to treat human immunodeficiency virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)

These medicines may be affected by Bactrim® 400/80, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Bactrim® 400/80.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bactrim® 400/80.

How to use Bactrim® 400/80

How much to take

Your doctor will decide what dose you will receive. The dose depends on your condition and other factors such as your age and weight.

Bactrim® 400/80 must always be diluted before use.
Bactrim® 400/80 is given as an intravenous infusion (i.e. a slow injection through a 'drip' into a vein) twice a day.
An infusion pump may be used to control the flow rate of the 'drip'.

This medicine should only be given by a doctor, nurse, or other trained person.

When to take it

Bactrim® 400/80 is administered twice per day.

How long to take it

Bactrim® 400/80 should be used ONLY during such periods as the patient is unable to accept oral therapy. In general, administration is unlikely to be required for more than a few days, and it is recommended that it be restricted to no more than three successive days.

If you forget to take it

As Bactrim® 400/80 is given to you under the supervision of your doctor, it is very unlikely that a dose will be missed. Your doctor or pharmacist has information on how what to do if a dose has been missed.

While you are using Bactrim® 400/80

Things you must do

Call your doctor straight away if you:

- Get severe diarrhoea, even if this occurs several weeks after treatment with Bactrim® 400/80 has stopped. Do not take diarrhoea medicine without first checking with your doctor.
- Become pregnant whilst being treated, or soon after being treated with Bactrim® 400/80. Bactrim® 400/80 is not recommended for use during pregnancy.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Bactrim® 400/80.

Things you must not do

Your doctor or nurse will advise if there are things you should be avoiding whilst being treated with Bactrim® 400/80.

Do not give Bactrim® 400/80 to anyone else, even if they have the same condition as you.

Things to be careful of

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Bactrim® 400/80 is not recommended for use during pregnancy. If there is a need to consider Bactrim® 400/80 during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of being given it. You may require a folic acid supplement to reduce the risk of harm to your unborn baby.

Talk to your doctor if you are breast-feeding or intend to breast-feed.
Sulfamethoxazole/trimethoprim passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. If there is a need to consider Bactrim® 400/80 while you are breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of you being given it.

Use in elderly patients

The use of Bactrim® 400/80 in elderly patients carries an increased risk of severe adverse reactions. Your doctor or pharmacist will discuss with you the benefits and risks of Bactrim® 400/80.

Use to treat sore throat

Sulfonamides should generally not be used to treat a sore throat, specifically suspected or confirmed streptococcal infections.

Anticoagulant activity

Anticoagulant activity may be increased by concurrent treatment with Bactrim® 400/80. This interaction should be kept in mind, and the coagulation time should be monitored.

Use with sulfonylureas

Concomitant use of Bactrim® 400/80 with sulfonylureas may result in worsening of hypoglycaemia in occasional patients.

Driving or using machines
Be careful before you drive or use any machines or tools until you know how Bactrim® 400/80 affects you.
Bactrim® 400/80 may cause dizziness in some people.

Drinking alcohol
Tell your doctor if you drink alcohol.
Heavy alcohol use may increase the chance of experiencing a serious side effect.

In case of overdose

If you take too much (overdose)

As Bactrim® 400/80 is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Your doctor or pharmacist has information on how to recognize and treat an overdose.

Ask your doctor or pharmacist if you have any concerns.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Bactrim® 400/80.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Bactrim® 400/80.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

If you are over 65 years of age you may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	**What to do**
• Pain or swelling at the injection site • Nausea or vomiting • Loss of appetite • Abdominal pain • Diarrhoea • Soreness of the mouth • Increased sensitivity of skin to the sun (sunburn) • Increased or decreased frequency of urination • Headache • Insomnia (difficulty sleeping) • Fatigue • Dizziness • Ringing in the ears	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Severe blisters and bleeding in the lips, eyes, mouth, nose or genitals • Itchy spots or red, painful rash or lumps under the skin, accompanied by a fast heartbeat, fever, weight loss and feeling unwell • Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, throat or other parts of the body, shortness of breath, wheezing or trouble breathing • Sore throat, fever or shortness of breath • Pain or aches in the joints • Fever, chills, cough, shortness of breath, phlegm and occasionally coughing blood • Pale skin • Unusual bleeding or bruising under the skin • Yellowing of the skin or whites of the eyes • Discolouration of urine or bowel motions • Renal stones Low sugar (glucose) levels in the blood: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat • Temporary paralysis or weakness of muscles	**Call your doctor straight away.**

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Bactrim® 400/80

Storage

The hospital staff will store your medicine appropriately.

Disposal

The hospital staff will dispose of any unused Bactrim® 400/80.
They will also check that the expiry date has not passed.

Product description

What it looks like

Bactrim® 400/80 is a clear and colourless to slightly yellow-ish liquid. It must always be diluted before use and should not be used if there are any crystals or cloudiness in the solution. Bactrim® 400/80 is contained in a small, glass ampoule.

Bactrim® 400/80 is supplied in a box of 10 x 5 mL ampoules.

Ingredients

Active ingredient(s):

- Sulfamethoxazole
- Trimethoprim

Inactive ingredients:

- Monoethanolamine
- Propylene glycol
- Alcohol
- Sodium hydroxide
- Water for injections

Do not take this medicine if you are allergic to any of the active or other ingredients.

Sponsor Details

Bactrim® 400/80 is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd
t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Mangere
Auckland 2022
NEW ZEALAND

Telephone (09) 918 5100

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