

Bactrim[®] 400/80 (sulfamethoxazole 400 mg/5 mL and trimethoprim 80 mg/5 mL concentrate for solution for infusion)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Bactrim[®] 400/80?

Bactrim[®] 400/80 contains the active ingredients sulfamethoxazole and trimethoprim. Bactrim[®] 400/80 is used to treat infections where the oral dosage form of the antibiotic is not appropriate.

For more information, see Section [1. Why am I using Bactrim[®] 400/80?](#) in the full CMI.

2. What should I know before I use Bactrim[®] 400/80?

Do not use if you have ever had an allergic reaction to Bactrim[®] 400/80 or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breast-feeding.

For more information, see Section [2. What should I know before I use Bactrim[®] 400/80?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bactrim[®] 400/80 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Bactrim[®] 400/80?

Bactrim[®] 400/80 will be administered to you by a doctor, nurse or other trained professional.

More instructions can be found in Section [4. How do I use Bactrim[®] 400/80?](#) in the full CMI.

5. What should I know while using Bactrim[®] 400/80?

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|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• 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 within one month of being treated with Bactrim[®] 400/80. Bactrim[®] 400/80 is not recommended for use during pregnancy. |
| Things you should not do | <ul style="list-style-type: none">• Your doctor or nurse will advise if there are things you should be avoiding whilst being treated with Bactrim[®] 400/80. |
| Driving or using machines | <ul style="list-style-type: none">• 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 | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Heavy alcohol use may increase the chance of experiencing a serious side effect. |
| Looking after your medicine | <ul style="list-style-type: none">• The hospital staff will store your medicine appropriately and also dispose of any unused Bactrim[®] 400/80. |

For more information, see Section [5. What should I know while using Bactrim[®] 400/80?](#) in the full CMI.

6. Are there any side effects?

Bactrim[®] 400/80 may cause side effects in some people, some of which include severe skin rashes, allergy, bleeding and bruising, low blood sugar and kidney impairment.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Bactrim[®] 400/80 (sulfamethoxazole 400 mg/5 mL and trimethoprim 80 mg/5 mL concentrate for solution for infusion)

(BAC-trem)

Active ingredient(s): *sulfamethoxazole, trimethoprim*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bactrim[®] 400/80. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Bactrim[®] 400/80.**

Where to find information in this leaflet:

- [1. Why am I using Bactrim[®] 400/80?](#)
- [2. What should I know before I use Bactrim[®] 400/80?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Bactrim[®] 400/80?](#)
- [5. What should I know while using Bactrim[®] 400/80?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Bactrim[®] 400/80?

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 is alone.

Bactrim[®] 400/80 concentrate for solution for infusion is used to treat infections where the oral dosage form of the antibiotic is not appropriate.

2. What should I know before I use Bactrim[®] 400/80?

Warnings

Do not use Bactrim[®] 400/80 if you:

- are allergic to trimethoprim
- are allergic to sulfamethoxazole or drugs containing 'sulfa'.
- are allergic to any of the ingredients listed at the end of this leaflet.
- have severe liver disease
- have abnormal cells in the blood
- have severe kidney disease
- have abnormal red blood cells (anaemias) associated with low levels of folic acid

- a low platelet count with bleeding or bruising more easily than normal with previous use of trimethoprim and/or sulfonamides
- are taking Dofetilide, used to treat heart arrhythmias

Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have any other medical conditions including
 - a deficiency of the enzyme glucose-6-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
 - phenylketonuria
 - porphyria
 - thyroid disease
 - folate deficiency
- take any medicines for any other condition

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 [6. Are there any side effects?](#)

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Bactrim[®] 400/80 may interfere with each other. 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 Bactrim[®] 400/80 works. You may need different amounts of your medicine, or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given this medicine.

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.

4. How do I use Bactrim[®] 400/80?

How much is given

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

When is it given

- Bactrim[®] 400/80 is administered twice per day.

How is it given

- 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.

If a dose is missed

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.

If you are given too much Bactrim[®] 400/80

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.

The Poisons Information Centre can also provide advice for management of potential overdose (in Australia, call 13 11 26)

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Bactrim[®] 400/80?

Things you should 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.

Things you should not do

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

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.

Looking after your medicine

The hospital staff will store your medicine appropriately.

Getting rid of any unwanted medicine

The hospital staff will dispose of any unused Bactrim® 400/80.

They will also check that the expiry date has not passed.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • 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 | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

Call the emergency department immediately if you experience multiple symptoms such as fever, very low blood pressure, increased heart rate or confusion after taking this drug as it may be a sign of shock.

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • 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, | <p>Call your doctor straight away.</p> |

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| numbness, having a fast, pounding heartbeat • Temporary paralysis or weakness of muscles | |
|---|--|

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Bactrim® 400/80 contains

| | |
|---|---|
| Active ingredients (ingredients that make the medicine work) | Sulfamethoxazole Trimethoprim |
| Other ingredients (inactive ingredients) | Monoethanolamine Propylene glycol Alcohol Sodium hydroxide Water for injections |
| Potential allergens | Do not take this medicine if you are allergic to any of the active or other ingredients. |

Do not take this medicine if you are allergic to any of these ingredients.

What Bactrim® 400/80 looks like

Bactrim® 400/80 is a clear and colourless to slightly yellowish 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 (AUST R 367590).

Who distributes Bactrim® 400/80

Bactrim® 400/80 is supplied in Australia by:

This leaflet was prepared in December 2025