

DBL™ Sulfamethoxazole 400 mg and Trimethoprim 80 mg

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 DBL Sulfamethoxazole/Trimethoprim?

DBL™ Sulfamethoxazole 400 mg and Trimethoprim 80 mg (DBL Sulfamethoxazole/Trimethoprim) is an antibacterial medicine containing two different antibiotics, sulfamethoxazole and trimethoprim. It is used to treat infections where treatment with the oral dosage form of the medicine is not appropriate.

For more information, see Section [1. Why am I using DBL Sulfamethoxazole/Trimethoprim?](#) in the full CMI.

2. What should I know before I use DBL Sulfamethoxazole/Trimethoprim?

Do not use if you have ever had an allergic reaction to Sulfamethoxazole or Trimethoprim 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 breastfeeding.** For more information, see Section [2. What should I know before I use DBL Sulfamethoxazole/Trimethoprim?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Sulfamethoxazole/Trimethoprim 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 DBL Sulfamethoxazole/Trimethoprim?

- This medicine should only be given by a doctor or other trained person, and your doctor will decide your dose.
- DBL Sulfamethoxazole/Trimethoprim must always be diluted before use and is given as an intravenous infusion (i.e. a slow injection through a 'drip' into the vein) twice a day.

More instructions can be found in Section [4. How do I use DBL Sulfamethoxazole/Trimethoprim?](#) in the full CMI.

5. What should I know while using DBL Sulfamethoxazole/Trimethoprim?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using DBL Sulfamethoxazole/Trimethoprim.• If you get severe diarrhoea tell your doctor immediately.• If you become pregnant while being given Sulfamethoxazole/Trimethoprim, tell your doctor immediately.
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 DBL Sulfamethoxazole/Trimethoprim affects you.
Looking after your medicine	<ul style="list-style-type: none">• The hospital staff will store DBL Sulfamethoxazole/Trimethoprim in a cool, dry place at a temperature below 30°C, away from moisture, heat or sunlight.• It should not be refrigerated.• They will also check that the expiry date has not passed.

For more information, see Section [5. What should I know while using DBL Sulfamethoxazole/Trimethoprim?](#) in the full CMI.

6. Are there any side effects?

Side effects may include nausea, vomiting, headache, pain or swelling at the injection site, severe allergic reaction (noted by impact to your skin, breathing, tongue and lips), itchy or painful rash, or muscle weakness and aches, as well as fungal overgrowth and changes to potassium levels in your blood seen in a blood test. 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.

DBL™ Sulfamethoxazole and Trimethoprim

Active ingredient(s): *Sulfamethoxazole* (sul-fa-meth-OX-a-zole) and *Trimethoprim* (try-METH-oh-prim)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL™ Sulfamethoxazole 400 mg and Trimethoprim 80 mg (DBL Sulfamethoxazole/Trimethoprim). **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Sulfamethoxazole/Trimethoprim.**

Where to find information in this leaflet:

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

1. Why am I using DBL Sulfamethoxazole/Trimethoprim?

DBL Sulfamethoxazole/Trimethoprim is an antibacterial medicine containing two different antibiotics, sulfamethoxazole and trimethoprim.

Together, both drugs are more efficient than either one is alone.

DBL Sulfamethoxazole/Trimethoprim is used to treat infections where treatment with the oral dosage form of the antibiotic is not appropriate.

2. What should I know before I use DBL Sulfamethoxazole/Trimethoprim?

Warnings

Do not use DBL Sulfamethoxazole/Trimethoprim if:

- You are allergic to sulfamethoxazole or trimethoprim, or any of the ingredients listed at the end of this leaflet.
- Some people are allergic to 'sulfa' drugs.
- Sulfamethoxazole is a 'sulfa'-containing medicine.
- Symptoms of an allergic reaction to sulfamethoxazole and trimethoprim may include:
 - Cough, shortness of breath, wheezing or difficulty breathing
 - Swelling of the face, lips, tongue or other parts of the body
 - Rash, itching or hives on the skin

- Always check the ingredients to make sure you can use this medicine
- You have:
 - Severe liver disease
 - Abnormal cells in the blood
 - Severe kidney disease
 - 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

DBL Sulfamethoxazole/Trimethoprim should not be given to premature babies or newborn babies (up to 8 weeks old).

You must not be given DBL Sulfamethoxazole/Trimethoprim if you are taking dofetilide (a medicine used to treat irregular heartbeat) at the same time.

If you are not sure whether you should be given this medicine, talk to your doctor or pharmacist.

Check with your doctor if you:

- Have any other medical conditions, especially the following:
 - 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
 - Phenylketonuria
 - Porphyria
 - Thyroid disease
 - Folate deficiency
- Take any medicines for any other condition. Please see [Section 3. What if I am taking other medicines?](#) below.
- Have any allergies to any other medicines, especially those containing 'sulfas', or to any foods, preservatives or dyes.

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.](#)

DBL Sulfamethoxazole/ Trimethoprim is not recommended for use during pregnancy.

If there is a need to consider DBL Sulfamethoxazole/Trimethoprim 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 breastfeeding or intend to breastfeed.

Sulfamethoxazole and 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 Sulfamethoxazole/Trimethoprim while you are breastfeeding, your doctor or pharmacist will discuss with you the benefits and risks of you being given it.

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 may interfere with DBL Sulfamethoxazole/Trimethoprim and affect how it works.

- Some medicines and DBL Sulfamethoxazole/Trimethoprim may interfere with each other. These include:
 - Methotrexate
 - Medicines that change to 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 and dofetilide (medicines 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 (i.e. calcium folinate – a medicine sometimes used with immune suppressants or as part of cancer treatment)
 - Antithyroid medicines (i.e. thionamides) used to treat overactive thyroid
 - Tricyclic antidepressants (type of antidepressant medicines)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Sulfamethoxazole/Trimethoprim.

4. How do I use DBL Sulfamethoxazole/Trimethoprim?

How much to use

- DBL Sulfamethoxazole/ Trimethoprim must always be diluted before use and is given as an intravenous infusion (i.e. a slow injection through a 'drip' into the 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.
- Your doctor will decide what dose you will receive. This depends on your condition and other factors such as your age and weight.

If you use too much DBL Sulfamethoxazole/Trimethoprim

As DBL Sulfamethoxazole/Trimethoprim is given to you under the supervision of your doctor, pharmacist or nurse, it is very unlikely that you will receive too much. Your doctor or pharmacist has information on how to recognise and treat an overdose. However, if you think that you have used too much DBL Sulfamethoxazole/Trimethoprim, you may need urgent medical attention.

You should immediately:

- Phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), or
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.

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

5. What should I know while using DBL Sulfamethoxazole/Trimethoprim?

Things you should do

Call your doctor straight away if you:

- get severe diarrhoea. Do this even if it occurs several weeks after treatment with Sulfamethoxazole/Trimethoprim has been stopped.
 - Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.
 - Do not take diarrhoea medicine without first checking with your doctor.
- become pregnant while being given Sulfamethoxazole/Trimethoprim.

Remind any doctor, dentist or pharmacist you visit that you are using DBL Sulfamethoxazole/Trimethoprim.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Sulfamethoxazole/Trimethoprim affects you.

DBL Sulfamethoxazole/Trimethoprim may cause dizziness in some people

Looking after your medicine

The hospital staff will store DBL Sulfamethoxazole/Trimethoprim in a cool, dry place at a temperature below 30°C, away from moisture, heat or sunlight. It should not be refrigerated. They will also check that the expiry date has not passed.

It will be kept where young children cannot reach it.

When to discard your medicine

The hospital staff will dispose of any unused DBL Sulfamethoxazole/Trimethoprim.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, it will be taken to the pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Side Effects

Side Effect	What to do
<p>Gastrointestinal related symptoms:</p> <ul style="list-style-type: none"> • Nausea • Vomiting • Loss of appetite • Abdominal pain • Diarrhoea • Soreness of the mouth • Increased or decreased frequency of urination <p>Infection related symptoms:</p> <ul style="list-style-type: none"> • Fungal infections <p>Sleep and alertness related symptoms:</p> <ul style="list-style-type: none"> • Headache • Insomnia (difficulty sleeping) • Fatigue • Dizziness <p>Other symptoms:</p> <ul style="list-style-type: none"> • Pain or swelling at the injection site • Increased sensitivity of skin to the sun (sunburn) • Ringing in the ears. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>Skin, muscle, and related symptoms:</p>	<p>Call your doctor straight</p>

Side Effect	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 • Unusual bleeding or bruising under the skin • Yellowing of the skin or whites of the eyes • Temporary paralysis or muscle weakness <p>Allergic reaction symptoms:</p> <ul style="list-style-type: none"> • 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, cough, shortness of breath, wheezing or trouble breathing <p>Gastrointestinal symptoms</p> <ul style="list-style-type: none"> • Diarrhoea • Discolouration of urine or bowel motions • Kidney stones, characterised by pain when urinating and further medical examination <p>Infection related symptoms:</p> <ul style="list-style-type: none"> • Sore throat, fever chills, cough, phlegm and occasionally blood • Multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay <p>Alertness and sleep related symptoms:</p> <ul style="list-style-type: none"> • Confusion, loss of contact with reality and unable to think or judge clearly. <p>Other:</p> <ul style="list-style-type: none"> • Rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting • Deep, rapid breathing, pounding heartbeat, headache, severe anxiety, changes in vision, nausea, vomiting, abdominal pain, altered appetite and weight gain, muscle weakness, bone and joint pain 	<p>away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Side Effect	What to do
<ul style="list-style-type: none"> Low sugar (glucose) levels in the blood: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat 	

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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 in Australia.

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 DBL Sulfamethoxazole/Trimethoprim contains

Active ingredients (main ingredients)	Trimethoprim Sulfamethoxazole
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Propylene glycol Ethanol Sodium hydroxide Diethanolamine Sodium metabisulphite Water for injection
Allergens	<ul style="list-style-type: none"> Contains sulfites Contains alcohol 10% v/v

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

DBL Sulfamethoxazole/Trimethoprim does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Sulfamethoxazole/Trimethoprim looks like

DBL Sulfamethoxazole/Trimethoprim is a clear, colourless or slightly yellow liquid. It must always be diluted before use and should not be used if there are any crystals or cloudiness in the solution (Aust R 16293).

Who distributes DBL Sulfamethoxazole/Trimethoprim

Pfizer Australia Pty Ltd

Sydney NSW