

DBL™ Sulfamethoxazole 400 mg and Trimethoprim 80 mg

Sulfamethoxazole (sul-fa-meth-OX-a-zole) and trimethoprim (try-METH-oh-prim)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Sulfamethoxazole 400 mg and Trimethoprim 80 mg (DBL Sulfamethoxazole/Trimethoprim). 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 taking DBL Sulfamethoxazole/Trimethoprim against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What DBL Sulfamethoxazole/Trimethoprim is used for

DBL Sulfamethoxazole/Trimethoprim is an antibacterial product 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is not addictive.

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

Before you are given this medicine

When you must not be given it

You must not be given DBL Sulfamethoxazole/Trimethoprim if you have an allergy to:

- any medicine containing sulfamethoxazole
- any medicine containing trimethoprim
- 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.

You must not be given DBL Sulfamethoxazole/Trimethoprim if you have any of the following:

- 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.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, especially those containing 'sulfas.'
- any foods, preservatives or dyes.

Tell your doctor or pharmacist if you have recently (days or weeks) been given DBL Sulfamethoxazole/ Trimethoprim.

Your doctor or pharmacist will discuss with you the benefits and risks of you being given it again.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

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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.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

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 breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of you being given it.

Tell your doctor or pharmacist if you have or have had any 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL Sulfamethoxazole/Trimethoprim.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from

your pharmacy, supermarket or health food shop.

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 (calcium folinate)
- antithyroid medicines (thionamides) used to treat overactive thyroid
- tricyclic antidepressants.

These medicines may be affected by DBL

Sulfamethoxazole/Trimethoprim or may affect how well it 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.

How DBL Sulfamethoxazole/Trimethoprim is given

How it is given

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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.

How much is given

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 take too much (overdose)

As DBL

Sulfamethoxazole/Trimethoprim 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 recognise and treat an overdose.

Ask your doctor or pharmacist if you have any concerns.

In case of overdose, immediately contact the Poisons Information Centre for advice on management. (in Australia, call 13 11 26)

While you are being given DBL Sulfamethoxazole/Trimethoprim

Things you must do

If you get severe diarrhoea, tell your doctor, nurse or pharmacist immediately. 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.

If you become pregnant while being given Sulfamethoxazole/Trimethoprim, tell your doctor immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Sulfamethoxazole/Trimethoprim.

Sulfamethoxazole/Trimethoprim.

This medicine helps most people with infections, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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 lists of side effects.

You may not experience any of them.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- pain or swelling at the injection site
- nausea, vomiting, or loss of appetite
- abdominal pain
- diarrhoea
- soreness of the mouth
- fungal infections
- increased sensitivity of skin to the sun (sunburn)
- increased or decreased frequency of urination
- headache

- insomnia (difficulty sleeping)
- fatigue
- dizziness
- ringing in the ears.

Ask your doctor, or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist immediately if you notice any of the following:

- multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay
- 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, cough, shortness of breath, wheezing or trouble breathing
- sore throat, fever chills, cough, phlegm and occasionally blood
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- unusual bleeding or bruising under the skin
- yellowing of the skin or whites of the eyes
- discolouration of urine or bowel motions
- kidney 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 muscle weakness

- 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
- confusion, loss of contact with reality and unable to think or judge clearly.

These may be serious side effects. You may need urgent medical attention. DBL Sulfamethoxazole/Trimethoprim may also cause changes in the number of cells in your blood.

You may not have any side effects from this, but blood tests may indicate that it has occurred. Mostly these changes are mild and reversible when DBL Sulfamethoxazole/Trimethoprim is stopped.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

After using DBL Sulfamethoxazole/Trimethoprim

Storage

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

Disposal

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

Product description

What it looks like

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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.

Ingredients

Active ingredients:

- trimethoprim
- sulfamethoxazole.

Other ingredients:

- propylene glycol
- ethanol
- sodium hydroxide
- diethanolamine
- sodium metabisulphite
- water for injection.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizermedicalinformation.com.au

Australian Registration Numbers

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Sulfamethoxazole/Trimethoprim (5 x 5 mL ampoules): AUST R 16293.

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