DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP

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 400mg and Trimethoprim 80mg Concentrate Injection BP (**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 or pharmacist has weighed the risks of you being given DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP 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 in a safe place. You may need to read it again.

What DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP is used for

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP is an antibacterial product containing two different antibiotics, sulfamethoxazole and trimethoprim. Together, both drugs are more efficient than either one is alone.

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

Your doctor may have prescribed DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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 sulfamethoxazole/trimethoprim if you have an allergy to sulfamethoxazole, 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:

- 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 400mg and Trimethoprim 80mg Concentrate Injection BP 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 sulphonamides

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP should not be given to premature babies or newborn babies (up to 8 weeks old).

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 other substances, such as foods, preservatives or dyes.

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

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP is not recommended for use during pregnancy. If there is a need to consider 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
- rheumatoid arthritis
- kidney disease
- liver disease (hepatitis).

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP.

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 400mg and Trimethoprim 80mg Concentrate Injection BP may interfere with each other. These include:

- methotrexate
- medicines that change to acidity of the urine (eg 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
- cyclosporin, a medicine used to lower the immune system
- pyrimethamine, a medicine used in the treatment or prevention of malaria.

These medicines may be affected by DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP, 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 DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP.

How DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP is given

How it is given

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP must always be diluted before use and is given as an intravenous infusion (ie. 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'. Sulfamethoxazole and Trimethoprim Injection 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 400mg and Trimethoprim 80mg Concentrate Injection BP 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; in New Zealand call 0800 764 766)

While you are being given DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP

Things you must do

If you get severe diarrhoea, tell your doctor 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 400mg and Trimethoprim 80mg Concentrate Injection BP.

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP helps most people with infections, but it may have unwanted side effects in a few people. 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 side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

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:

- rash, itch or swelling of the skin
- sore throat, fever or shortness of breath
- pain or aches in the joints
- cough or shortness of breath
- pale skin
- unusual bleeding or bruising under the skin
- yellowing of the skin or whites of the eyes.
- discolouration of urine

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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 or vomiting.
- 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.

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 Sulfamethoxazole and Trimethoprim Injection is stopped.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP

Storage

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 30°C. It should not be refrigerated..

Product description

What it looks like

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP 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
- absolute alcohol
- sodium hydroxide
- diethanolamine
- sodium metabisulphite
- water for injection.

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

Supplier / Sponsor

NAME AND ADDRESS OF SPONSOR

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330

Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive,
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Sulfamethoxazole 400mg and Trimethoprim 80mg Concentrate Injection BP is available in the following strength:

- Sulfamethoxazole 400mg and Trimethoprim 80mg.
  5 x 5mL ampoules.
  AUST R 16293

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