

## TRISUL

**Co-trimoxazole 480mg Tablets**

**(Trimethoprim 80mg / Sulphamethoxazole 400mg)**



### What is in this leaflet

This leaflet answers some common questions about TRISUL.

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 TRISUL 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 TRISUL is used for

TRISUL contains two active ingredients, trimethoprim and sulphamethoxazole. They belong to a group of medicines known as antibiotics and work by stopping the growth of bacteria that is causing your infection.

TRISUL is used to treat infections of the urinary tract, upper and lower respiratory tract and bowel.

Your doctor may, however, prescribe TRISUL for another reason. **Ask your doctor if you have any questions about why TRISUL has been prescribed for you.**

There is no evidence that TRISUL is addictive.

TRISUL is available on prescription from your doctor.

This medicine is not expected to affect your ability to drive a car or operate machinery.

### Before you take TRISUL

#### When you must not take it:

Do not take TRISUL if:

- You have severe liver or kidney disease
- You have a low red blood cell count (anaemia)
- You have a low white blood cell count
- You have a low platelet count or other serious blood disorders

**TRISUL should not be given to premature babies or to full term infants under 4 weeks of age.**

#### Do not take TRISUL if you have an allergy to:

- Any medicine containing trimethoprim or sulphamethoxazole
- Any sulphonamide or sulfur containing antibiotic
- Any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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.

**Do not take this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### **Before you start to take it:**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- Liver problems
- Kidney problems
- Any blood disorder (including porphyria and glucose-6-phosphate dehydrogenase deficiency)
- Epilepsy (fits or seizures)
- Asthma or other respiratory tract problems
- Rheumatoid arthritis
- Malabsorption syndrome or suffer from malnutrition
- Folate deficiency (low folate levels)

**Tell your doctor immediately if you are pregnant or plan to become pregnant, or are breast-feeding or plan to breastfeed.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell him/her before you start taking TRISUL.**

#### **Taking other medicines**

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

Some medicines and TRISUL may interfere with each other. These include:

- Sulphonylureas, medicines used to treat diabetes
- Diuretics (fluid tablets), mainly thiazide type diuretics
- Phenytoin, a medicine used to control epilepsy (fits or seizures)
- Rifampicin, an antibiotic
- Warfarin, a medicine used to prevent or treat blood clots
- Cyclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system
- Methotrexate, a medicine used to treat arthritis, psoriasis and some cancers
- Digoxin, a medicine used to treat heart failure or to control a fast irregular heart beat
- Procainamide, a medicine used to correct an irregular heart beat or to slow an overactive heart beat
- Amantadine, a medicine used to treat Parkinson's disease
- Zidovudine or lamivudine, medicines used to treat HIV infection
- Potassium supplements

These medicines may be affected by TRISUL or may affect how well TRISUL works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take TRISUL

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

### ***How much to take***

Your doctor will tell you how much TRISUL you need to take each day. It is important that you take TRISUL as directed by your doctor. Do not take more than the recommended dose.

The usual dose for adults and children over 12 years is two TRISUL tablets every 12 hours.

TRISUL is used for different reasons and for different infections. Your doctor may tell you to take different doses to these. If so, follow their instructions.

The elderly and people with kidney problems may need smaller doses.

Some people may need to take folate supplements while taking TRISUL. These people may include the elderly, people with folate deficiency and people taking certain medicines.

### ***How to take it***

It does not matter if you take this medicine before or after food.

However, taking TRISUL with some food or drink will lessen the chance of stomach upset.

### ***How long to take it***

Your doctor will tell you how long they wish you to continue TRISUL treatment for. Most infections need treatment for at least 5 days.

Some conditions may however, may require treatment to be longer than this. Check with your doctor if you are unsure how long you should take TRISUL for.

### ***If you forget to take it***

If you forget a dose, skip the dose you missed and take the next dose when it is due.

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TRISUL. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, dizziness and confusion.

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## While you are taking TRISUL

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### ***Things you must do***

**If you develop any skin rash (e.g. spots or 'hives') or other skin symptoms during TRISUL treatment contact your doctor immediately and tell them that you are taking TRISUL.**

There are reports of skin rash associated with TRISUL treatment. Some of these may be serious and cause severe illness.

These include potentially life-threatening skin rashes such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). **These skin rashes may appear initially as reddish target-like spots or circular patches often with central blisters on the trunk.**

**Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).**

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

**If you have developed Stevens-Johnson syndrome or toxic**

epidermal necrolysis with the use of TRISUL, Co-Trimoxazole, or Sulfamethoxazole, you must not be re-started on these medicines at any time.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TRISUL.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Tell your doctor immediately if you develop a skin rash or hives while taking TRISUL.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TRISUL.

If you are going to have any blood tests, tell your doctor that you are taking TRISUL.

Do not stop taking TRISUL or change the dose without first checking with your doctor.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (for example blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

### **Things you must not do**

Do not take TRISUL to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar to yours, or they have the same condition as you.

Do not stop taking your medicine or change the dose without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

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## Side effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TRISUL.

This medicine 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.

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

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

- Feeling sick, vomiting, stomach upset, diarrhoea
- Oral thrush (white, furry sore tongue and mouth)
- Vaginal thrush (sore and itchy vagina, vaginal discharge)
- Headache
- Dizziness or feeling unsteady
- Muscle or joint aches
- Increased sensitivity to sunlight

The above list includes the more common side effects of your medicine.

They are often mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Watery and severe diarrhoea, which may also be bloody
- Severe stomach cramps
- Unusual tiredness or weakness and looking pale
- Bruising or bleeding more easily than normal

- Signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- Severe and persistent headache
- Tingling or numbness in the hands and feet
- Cough, shortness of breath

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Any skin reaction, redness, itching, swelling or blistering of the skin (e.g. skin rash, 'hives', spots, or blisters)
- Swelling of the face, lips or tongue
- Sore mouth or sore eyes
- A high temperature (fever)
- Yellowing of the eyes or skin (jaundice)
- Passing very little or no urine
- Seizures or fits

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, blood disorders and high potassium levels) can only be found when your doctor does tests from time to time to check your progress.

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## After using TRISUL

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### **Storage**

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store TRISUL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

***Disposal***

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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**Product description**

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***What it looks like***

TRISUL tablets are white, biconvex tablets, 11 mm diameter. Imprinted with "CE 80/400" with a score-line on the same side and blank on the other side.

***Ingredients***

Each TRISUL tablet contains 80 mg of trimethoprim and 400mg of co-trimoxazole as the active ingredients.

It also contains:

- Povidone
- Sodium starch glycollate
- Magnesium stearate
- Docusate sodium

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

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**If you want to know more**

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland 1542

Telephone: (09) 579 2792

***Date of Information***

25 November 2011 (Based on datasheet dated 25 November 2011)