

NEW ZEALAND CONSUMER MEDICINE INFORMATION

TRISUL

Co-trimoxazole 480mg Tablets

(Sulfamethoxazole 400mg / Trimethoprim 80mg)



What is in this leaflet

Please read this leaflet carefully before you start taking TRISUL.

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

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

Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that TRISUL is addictive.

TRISUL is available only with a doctor's prescription.

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
- You have other serious blood disorders, e.g. acute porphyria
- You need treatment for a streptococcal pharyngitis (throat infection)
- You are already taking dofetilide (a medicine that helps with irregular heartbeats). Talk to your doctor for advice on what to do.

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

Do not take TRISUL if you have an allergy to:

- Any medicine containing trimethoprim or sulfamethoxazole
- Any sulfonamide 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.

Talk to your doctor about discontinuation of the medicine if a skin rash appears. Clinical signs such as rash, sore throat, fever, joint pain, cough, shortness of breath, pallor, blood spots on skin or yellowing of skin (jaundice) may be early indications of serious reaction.

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 glucose-6-phosphate dehydrogenase deficiency and thrombocytopenia)
- Epilepsy (fits or seizures)
- Asthma or other respiratory tract problems
- Rheumatoid arthritis
- Malabsorption syndrome or suffer from malnutrition
- Folate deficiency (low folate levels)
- Pneumonia if you have HIV

- Thyroid problems.

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 them before you start taking TRISUL.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking TRISUL.

Some medicines may interfere with TRISUL. These include:

- Sulfonylureas, or other medicines used to treat diabetes
- Diuretics (fluid tablets), mainly thiazide type and spironolactone diuretics
- Phenytoin, a medicine used to control epilepsy (fits or seizures)
- Rifampicin, an antibiotic
- Warfarin or other blood thinners, medicines used to prevent or treat blood clots
- Ciclosporin, 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 heartbeat
- Procainamide, a medicine used to correct an irregular heartbeat or to slow an overactive heartbeat
- Amantadine, a medicine used to treat Parkinson's disease
- Zidovudine or lamivudine, medicines used to treat HIV infection
- Potassium supplements

- Pyrimethamine, a medicine used to treat parasitic diseases such as malaria
- Repaglinide, a medicine used to control diabetes
- Folinic acid, a medicine used to treat bowel cancer
- Oral contraceptives, medicines used to control fertility
- Azathioprine, a medicine to treat inflammations
- Tricyclic antidepressants used to treat depression
- Dofetilide used to treat irregular heartbeats
- Medications to help lower blood pressure or treat other heart conditions (such as ACE inhibitors and Angiotensin receptor blockers)
- Prednisolone – a steroid medication
- Indomethacin, phenylbutazone or oxyphenbutazone – certain types of anti-inflammatory medicines

TRISUL and leucovorin should not be used together leucovorin for the treatment of HIV positive patients with pneumonia as the treatment will not work and increases the death rate from the pneumonia.

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.

How to take TRISUL

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 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.

While you are taking TRISUL

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 and toxic epidermal necrolysis. **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, 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, tell 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.

Be careful driving or operating machinery until you know how TRISUL affects you. This medicine may cause dizziness in some people. If you experience this side effect, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness may be worse.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your 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.

Side effects

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

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 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
- Have trouble sleeping or feel fatigued
- Reduced appetite
- Low blood pressure
- Vision problems
- Hair loss (alopecia)

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:

- Low sugars (glucose) levels in the blood for non-diabetic patients
- Lack of general interest, nervousness, mental depression or hallucinations
- Watery and severe diarrhoea, which may also be bloody
- Severe stomach cramps
- Unusual tiredness or weakness and looking pale
- 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
- Pain and inflammation of one or both eyes

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)
- Purple, blotchy or easily bruised skin
- Swelling of the face, lips or tongue
- Sore mouth, throat, or sore eyes
- Red and swollen eyes
- Blurred vision
- A high temperature (fever)
- Yellowing of the eyes or skin (jaundice)
- Passing very little or no urine
- Seizures or fits
- Pain in joints
- Cough, shortness of breath
- Severely low blood pressure
- Confusion
- Stomachache
- Swollen lymph nodes

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

TRISUL should be discontinued if a skin rash appears and an alternative treatment should be considered by your doctor.

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 patients. Tell your doctor if you notice any other effects.

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

Some of these side effects (for example, blood disorders and high potassium levels) can only be found when your doctor does tests to check your progress. Complete blood counts should be done frequently. If a significant reduction in the blood count is noted, TRISUL should be discontinued.

After using TRISUL

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.

Product description

What it looks like

TRISUL tablets are 11 mm flat bevelled edge white tablets, marked "801400" on one side and "R" on the *other side* Ingredients

Ingredients

Active ingredients:

Each TRISUL tablet contains 400 mg of sulfamethoxazole and 80 mg of trimethoprim as the active ingredients.

Inactive ingredients:

Trisul also contains:

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

Contains sulfites.

If you want to know more

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

Who supplies this medicine

TRISUL is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of preparation

10 February 2023 (Based on datasheet dated 10 February 2023)