

210mm



**Package leaflet: Information for the user**  
**TRIMETHOPRIM 50 mg / 5 ml Suspension**  
**Trimethoprim**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Trimethoprim is and what it is used for
2. What you need to know before you take Trimethoprim
3. How to take Trimethoprim
4. Possible side effects
5. How to store Trimethoprim
6. Contents of the pack and other information

**1. What Trimethoprim is and what it is used for**

Trimethoprim is an antibiotic which is used to treat or prevent bacterial infections, including urinary tract infections, in adults and children.

**2. What you need to know before you take Trimethoprim**

**Do not take Trimethoprim:**

- If you are allergic to trimethoprim or any of the ingredients of this medicine (*listed in Section 6*).
- If you are pregnant or might be pregnant, or if you are breast-feeding long-term.
- If you have anaemia or other serious blood disorders.
- If you have severe liver problems.

**Warnings and precautions**

**Talk to your doctor before taking Trimethoprim:**

- If you have folate deficiency anaemia (especially in the elderly).
- If you have or might have had acute Porphyria (blood disorders).
- If you suffer from kidney problems or are having dialysis treatment.
- If you are also taking repaglinide (medicine for treating diabetes).
- If you have fructose intolerance or an intolerance to some sugars.

Trimethoprim can increase potassium blood levels. Patients at risk of increased potassium blood levels include those with kidney problems, poorly controlled diabetes, or those on certain medicines or potassium supplements. The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache. Your doctor may perform blood tests to monitor your potassium blood levels.

Your doctor may wish to do regular blood tests if you need long-term treatments or are prone to anaemia.

**Other medicines and Trimethoprim**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular:

- Folate antagonists, used to treat folate deficiency (e.g. aminopterin or methotrexate)
- Bone Marrow depressants (e.g. azathioprine, cytarabine, or daunorubicin)
- Repaglinide, used to treat diabetes
- Procainamide, to treat abnormal heart rhythm
- Digoxin, to treat heart conditions
- Diuretics (e.g. water tablets such as eplerenone, spironolactone, amiloride or triamterene)
- Rifampicin, used to treat TB
- Anticoagulants (to prevent clots from forming in the blood e.g. warfarin)
- Phenytoin to treat epilepsy
- Pyrimethamine and dapsone, used to treat malaria
- Immunosuppressant drugs – used in cancer treatment (e.g. methotrexate) or to treat organ rejection after transplant (e.g. azathioprine or ciclosporin).
- Potassium supplements
- Medicines known as ACE inhibitors and angiotensin II antagonists (used to treat high blood pressure and certain heart conditions).
- Heparin (used to treat and prevent blood clots)

**Trimethoprim with food and drink:**

Trimethoprim can be taken with or without food.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be taken during pregnancy. Ask your doctor or pharmacist for advice if you are pregnant or planning on becoming pregnant or are breast-feeding long term.

**Trimethoprim contains sorbitol (E420), methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216)**

- **Sorbitol (E420):** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216):** may cause allergic reactions (possibly delayed).

**3. How to take Trimethoprim**

Always take Trimethoprim exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Shake well before use.

The recommended dose is:

<b>Adults (including the elderly) and children over 12 years of age:</b>		
Urinary tract infections and other susceptible infections	Four 5 ml spoonfuls twice daily	
Long-term prevention of recurring urinary tract infections	Two 5 ml spoonfuls at night	
<b>Children 6 weeks to 12 years of age:</b>		
Urinary tract infections and other susceptible infections	6 weeks - 5 months	2.5 ml (half a 5 ml spoonful) twice daily
	6 months - 5 years	One 5 ml spoonful twice daily
	6 years - 12 years	Two 5 ml spoonfuls twice daily
Long-term prevention of recurring urinary tract infections	6 months - 5 years	2.5 ml spoonful (half a 5 ml spoonful) at night
	6 years - 12 years	One 5 ml spoonful at night

23LF01663PW



210mm



**Elderly**

The adult dose may need to be reduced depending on how well your kidneys function. Your doctor will advise you.

**Renal Impairment**

It may be necessary to reduce the dosage if you are suffering from kidney problems. Your doctor will advise you.

**If you forget to take Trimethoprim**

Take the missed dose as soon as you remember, unless its nearly time for your next dose. Do not take a double dose to make up for the missed dose.

**If you take more Trimethoprim than you should**

If you take too much Trimethoprim, go immediately to your nearest hospital casualty department, taking your medicine bottle with you to show what you have taken.

**If you stop taking Trimethoprim**

Remember to keep taking this medicine until your doctor tells you to stop. **Do not** stop just because you feel better. If you stop too early, your infection may return, or get worse.

If you have any further questions on the use of Trimethoprim, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor or hospital at once** if you get an allergic reaction such as swelling of the face, lips, tongue or throat, difficulty breathing, shock or collapse. Aseptic meningitis can occur in some patients. This may show as a combination of symptoms such as headache, fever, stiff neck, tiredness, feeling ill and your eyes become very sensitive to bright light.

Severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (severe skin rash with flushing, fever, blisters and ulcers), toxic epidermal necrolysis (severe rash involving reddening, peeling and swelling of the skin that resembles severe burns), may also be signs of an allergic reaction.

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Common** (occurs in more than 1 in 10 and less than 1 in 100 people)

- feeling and being sick, diarrhoea
- High levels of potassium in the blood (may result in abnormal heart rhythm)
- Sore throats or mouth ulcers (due to a decrease in white blood cells)

- Headache
- Skin rashes
- Thrush.

**Very rare** (occurs in less than 1 in 10,000 people)

- Constipation, severe watery/bloody diarrhoea
- Agitation
- Abnormal behaviour
- Kidney problems (signs may include painful urination or blood in the urine)
- Convulsions
- Pins and needles, shakiness
- Eye redness and pain
- Low levels of sodium in the blood (may cause nausea, tiredness, muscle cramping)
- Weight loss
- Elevation of serum transaminases (an indication of liver damage)
- Elevation of bilirubin levels
- Meningitis (signs may include stiff neck, fever and vomiting)

- Cough
- Jaundice (yellowing of the skin or whites of the eyes)
- Dizziness, tiredness
- Involuntary movements
- Ringing in the ears, vertigo
- Increased sensitivity of the skin to the sun
- Low blood sugar
- Depression, anxiety, sleeping difficulties, nightmares
- Confusion, hallucinations
- Joint and muscle ache
- Wheezing, nosebleeds
- Lupus erythematosus (an auto-immune disorder).

**Unknown**

- Anaemia (may cause you to feel tired and look pale)
- Elevated levels of methaemoglobin (may cause shortness of breath, tiredness, headache and dizziness)
- Sore tongue and mouth
- Gastro-intestinal disturbance
- Itching.

**Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Trimethoprim**

Keep this medicine out of the sight and reach of children. Store in the original container. Do not use this medicine after the expiry date which is stated on the label or carton. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Trimethoprim contains:**

- the **active substance** is trimethoprim; each 5 ml of the oral suspension contains trimethoprim 50 mg.
- the **other ingredients** are agar, polysorbate 80, saccharin sodium, sorbitol (E420), methylhydroxybenzoate (E218), propylhydroxybenzoate (E216) and purified water (*see end of Section 2*).

**What Trimethoprim looks like and contents of the pack**

Trimethoprim is a white, opalescent, viscous oral suspension. This medicine contains no flavour. It is available in 100 ml amber glass bottles with pilfer-proof screw cap and expanded polyethylene liner.

**Marketing Authorisation Holder and Manufacturer**

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

PL04917/0065

This leaflet was last updated in 06/2019

23LF01663PW



VENDOR CODE TO BE PRINTED AT THE BOTTOM RIGHT HAND CORNER OF FRONT AND BACK PAGE

PRINT FREE AREA

BLEED AREA

297mm

297mm

3mm

14mm

3mm

14mm