



PACKAGE LEAFLET: INFORMATION FOR THE USER

Trimethoprim 100mg Tablets
Trimethoprim 200mg Tablets
(trimethoprim)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Trimethoprim Tablets are and what they are used for
2. Before you take Trimethoprim Tablets
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4. Possible side effects
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1. WHAT TRIMETHOPRIM TABLETS ARE AND WHAT THEY ARE USED FOR

Trimethoprim is a broad spectrum agent which belongs to a group of medicines called "anti-infectives". It kills a wide range of bacteria, and is used for treating and preventing bacterial infections of the bladder or urinary tract.

2. BEFORE YOU TAKE TRIMETHOPRIM TABLETS

Do NOT take Trimethoprim Tablets if you:

- have an allergy (hypersensitivity) to trimethoprim or any of the other ingredients in the product (see *Section 6 and end of Section 2*)
- have severe liver problems
- are **pregnant**
- have severe kidney impairment
- have megaloblastic anaemia or other blood abnormalities.
- Trimethoprim should NOT be given to premature **babies or children** under 4 months old.

Take special care with Trimethoprim Tablets

Tell your doctor if you have problems with **kidney** function; regular **blood tests** are needed if you are receiving long-term treatment of trimethoprim or are prone to folate deficiency.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- antibiotics such as rifampicin
- anticoagulants to prevent your blood clotting such as warfarin
- ciclosporin (to prevent rejection after transplantation)
- digoxin (to treat heart conditions)
- phenytoin (to treat epilepsy)
- pyrimethamine (to treat malaria)
- bone marrow depressants.

Pregnancy and breast-feeding

Trimethoprim should not be used in pregnancy.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Trimethoprim Tablets are not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Trimethoprim Tablets

This product contains lactose – if you know you have an intolerance to some sugars, contact your doctor before use.

3. HOW TO TAKE TRIMETHOPRIM TABLETS

For **oral use** only.

Always take trimethoprim tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with a glass of water at the same times each day.

Doses:

- **Severe or sudden infections:** (e.g. uncomplicated bacterial cystitis in women) treatment will usually be between 3-14 days, according to the type and severity of infection.

Your doctor may double your first dose.

- Adults and children over 12 years: 200mg twice a day.
- Children 6-12 years: 100mg twice a day.
- Children under 6 years: Not recommended; a more suitable dosage form should be used in this age group.

• **Long-term treatment and prevention therapy:**

- Adults and children over 12 years: 100mg at night.
- Children 6-12 years: 50mg at night. The usual dose is around 2mg per kg body weight of the child per day.

Elderly: doses may be reduced in elderly patients, according to kidney function.

If you take more Trimethoprim Tablets than you should

Contact your doctor or nearest hospital causality department if you or a child has accidentally swallowed too many tablets. Take this leaflet and any remaining tablets with you, if possible.

If you forget to take Trimethoprim Tablets

If you miss a dose, just carry on with the next dose as normal. Do not take a double dose to make up for the forgotten one.

If you stop taking Trimethoprim Tablets

Do not stop treatment without talking to your doctor first, even if you feel better.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Trimethoprim Tablets can cause side effects, although not everyone gets them.

Stop taking the tablets immediately and seek urgent medical advice if the following occur:

- **Allergic reaction** symptoms of which may include hives (also known as nettle rash or urticaria), difficulty in breathing, swelling of the face, lips, throat or tongue, or collapse.
- **Aseptic meningitis** which 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 or ulcers) or toxic epidermal necrolysis (severe rash involving reddening, peeling and swelling of the skin that resembles severe burns)

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Blood: altered number and type of certain blood cells. If you get increased bruising, nose bleeds, sore throats or infections you should consult your doctor. Too much potassium in the blood (you may experience muscle cramps or pain, irregular heartbeats, unusual tiredness or weakness).

Stomach: feeling or being sick, this is usually mild and disappears after stopping the tablets.

Skin: sensitivity to light, skin rashes which may be itchy.

Liver: changes in liver enzymes (seen in tests), jaundice (yellowing of skin or whites of the eyes).

Kidney: increase in blood creatinine and urea.

Muscles: muscle pain

Other: Headache, red, swollen tongue.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TRIMETHOPRIM TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in a dry place in the original container.

Do not use Trimethoprim Tablets after the expiry date which is printed on the carton after 'EXP' (the expiry date refers to the last day of the month stated).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Trimethoprim Tablets contain

The active substance is trimethoprim.

The **other** ingredients are lactose, povidone 25cps, crospovidone, sodium starch glycollate and magnesium stearate (see Section 2 'Important information about some of the ingredients of Trimethoprim Tablets').

What Trimethoprim Tablets look like and contents of the pack

The tablets are white, flat and bevelled edge, engraved with 'MT100' (100mg) or 'MT200' (200mg).

They are available in container packs of 50, 100, 500, 1000 and 5000 tablets as well as in blister pack of 28 tablets. The 200mg strength is also available in blister packs of 6 and 14 tablets (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Milpharm Limited,
Ares, Odyssey Business Park,
West End Road,
South Ruislip, HA4 6QD
United Kingdom

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