

TRIMETHOPRIM VIATRIS

trimethoprim

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about TRIMETHOPRIM VIATRIS.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TRIMETHOPRIM VIATRIS against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What TRIMETHOPRIM VIATRIS is used for

TRIMETHOPRIM VIATRIS contains the active ingredient called trimethoprim which belongs to a group of medicines called antibiotics. TRIMETHOPRIM VIATRIS is used to treat urinary tract infections caused by bacteria. It works by stopping the growth of the bacteria that is causing your infection.

Use TRIMETHOPRIM VIATRIS only as directed and consult a health care professional if pain or symptoms persist.

TRIMETHOPRIM VIATRIS will not work against infections caused by viruses, such as colds or flu.

Ask your doctor if you have any questions about why TRIMETHOPRIM VIATRIS has been prescribed for you.

Your doctor may have prescribed TRIMETHOPRIM VIATRIS for another reason.

TRIMETHOPRIM VIATRIS is available only with a doctor's prescription.

TRIMETHOPRIM VIATRIS should not be administered to premature babies or infants under 4 months of age.

TRIMETHOPRIM VIATRIS is not recommended for use in children under 6 years of age, as the safety and effectiveness of TRIMETHOPRIM VIATRIS in this age group has not been established.

Before you take TRIMETHOPRIM VIATRIS

When you must not take it

Do not take TRIMETHOPRIM VIATRIS if you are allergic to any other medicines containing trimethoprim or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include red, itchy skin rashes, itching or hives; swelling of the face, lips, throat, or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath; faintness.

Do not take TRIMETHOPRIM VIATRIS if you have:

- a severe blood disorder or anaemia
- severe kidney problems.

Do not take TRIMETHOPRIM VIATRIS after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date, it may not work as well.

Do not take TRIMETHOPRIM VIATRIS if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

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 are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

TRIMETHOPRIM VIATRIS is rated in Australia as a Category B3 drug for use in pregnancy. Ask your doctor about the risks and benefits of taking TRIMETHOPRIM VIATRIS during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

TRIMETHOPRIM VIATRIS is able to pass into breast milk. There is a possibility that the breast-fed baby may be affected. Therefore, do not take TRIMETHOPRIM VIATRIS if you are breastfeeding or plan to breastfeed. Tell your

doctor if you have, or have had, any medical conditions, especially the following:

- folate deficiency
- kidney problems
- liver problems
- porphyria
- any type of blood disorder.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking TRIMETHOPRIM VIATRIS.

Taking other medicines

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

Some medicines may be affected by TRIMETHOPRIM VIATRIS, or may affect how well it works. These include:

- pyrimethamine, a medicine used to prevent malaria
- warfarin, a medicine used to prevent blood clots
- coumarins
- methotrexate, a medicine used to treat arthritis and some types of cancer
- phenytoin, a medicine used to control epilepsy (fits or seizures)
- 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 over active heart
- zidovudine, zalcitabine or lamivudine; medicines used for certain viral infections
- dapsone, a medicine used for leprosy or dermatitis herpetiformis
- rifampicin, an antibiotic
- cyclosporine, a medicine used to help prevent organ transplant

rejection or to treat certain problems with the immune system

- repaglinide, used to treat diabetes
- diuretics, also known as fluid or water tablets
- ACE inhibitors, medicines used to treat high blood pressure and some heart conditions.
- certain blood pressure medications that can increase potassium levels in the blood
- Folate antagonists and anticonvulsants

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

This list is not exhaustive. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking TRIMETHOPRIM VIATRIS.

Talk to your doctor about the need for additional contraception while taking TRIMETHOPRIM VIATRIS.

Some antibiotics may decrease the effectiveness of some birth control pills.

Tell your doctor or pharmacist that you are taking TRIMETHOPRIM VIATRIS before you start taking any other medicine.

How to take TRIMETHOPRIM VIATRIS

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

For adults and children over 12 years, the usual dose is one tablet daily.

For children 6 to 12 years, the usual dose is half a tablet daily.

Do not give TRIMETHOPRIM VIATRIS to children under the age of 6 years.

There is no information concerning the right dose for children under the age of 6 years.

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

Different people may respond differently to TRIMETHOPRIM VIATRIS, so your doctor may tell you to take a different dose.

Some people may need to take folate supplements while taking TRIMETHOPRIM VIATRIS. These people may include the elderly, people with folate deficiency and people taking certain medicines. Your doctor will tell you if this is necessary.

How to take TRIMETHOPRIM VIATRIS

Swallow the tablets whole with a glass of water.

When to take TRIMETHOPRIM VIATRIS

TRIMETHOPRIM VIATRIS can be taken with or without food. Taking TRIMETHOPRIM VIATRIS with food will help reduce the chance of a stomach upset.

TRIMETHOPRIM VIATRIS tablets are best taken before bedtime.

How long to take TRIMETHOPRIM VIATRIS for

Keep taking TRIMETHOPRIM VIATRIS until you finish the pack, or for as long as your doctor recommends.

For most infections, TRIMETHOPRIM VIATRIS is usually taken for 7 days.

Do not stop taking TRIMETHOPRIM VIATRIS, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

If you forget to take TRIMETHOPRIM VIATRIS

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much TRIMETHOPRIM VIATRIS (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much TRIMETHOPRIM VIATRIS.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much TRIMETHOPRIM VIATRIS, you may experience the following: nausea, vomiting, dizziness, headaches, confusion or mental depression.

While you are taking TRIMETHOPRIM VIATRIS

Things you must do

Immediately stop taking TRIMETHOPRIM VIATRIS if skin rash or any other allergic reaction occurs.

Before starting any new medicine, tell your doctor or pharmacist that you are taking TRIMETHOPRIM VIATRIS

Tell all the doctors, dentists and pharmacists who are treating you that you are taking TRIMETHOPRIM VIATRIS.

If you become pregnant while taking TRIMETHOPRIM VIATRIS, tell your doctor immediately.

If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you are taking TRIMETHOPRIM VIATRIS for a long time, visit your doctor regularly so that they can check on your progress.

You may need to have regular blood tests.

Always discuss with your doctor any problems or difficulties during or after taking TRIMETHOPRIM VIATRIS

Things you must not do

Do not take any other medicines while you are taking TRIMETHOPRIM VIATRIS without first telling your doctor.

Do not drive or operate machinery until you know how TRIMETHOPRIM VIATRIS affects you.

Do not use TRIMETHOPRIM VIATRIS to treat any other conditions unless your doctor tells you to.

Do not give TRIMETHOPRIM VIATRIS to anyone else, even if

they have the same condition as you.

Side effects

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

TRIMETHOPRIM VIATRIS helps most people with urinary tract infections, but it 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 treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- epigastric distress
- headache
- stomach upset
- nausea (feeling sick), vomiting
- vomiting.
- glossitis
- diarrhoea.
- sore tongue
- cough
- difficult sleeping
- dizziness, sleepiness, drowsiness
- fainting
- ringing, hissing, whistling, buzzing, or persisting noise in the ears
- joint or muscle pain
- nosebleeds

The above list includes the milder side effects of your medicine.

See your doctor immediately if you notice any of the following:

- any type of skin rash which includes itching and redness
- unusual bruising or bleeding
- tiredness which may occur together with headaches, sore mouth or tongue, weight loss or yellowing of the eyes or skin
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- Swelling of the face, lips, mouth, tongue and throat.
- shortness of breath, wheezing or difficulty breathing.
- depression, hallucinations, confusion, nervousness, feeling anxious
- Blurred vision, redness of the eye, eye pain, increased sensitivity to light.

The above list includes serious side effects which may require medical attention.

See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of an allergic reaction such as itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- redness, blistering, peeling or loosening of skin; bleeding of the lips, eyes, mouth, nose and genitals
- severe rash with skin peeling, fever, chills and aching muscles.
- blurred vision, redness of the eye, eye pain, increased sensitivity to light, uveitis (eye inflammation).

The side effects listed above are rare but serious and require urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects.

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

Check with your doctor as soon as possible if you have any problems while taking TRIMETHOPRIM VIATRIS even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After taking TRIMETHOPRIM VIATRIS

Storage

Keep TRIMETHOPRIM VIATRIS 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.

Keep your tablets in a cool dry place where the temperature stays below 30°C and protect from light.

Do not store TRIMETHOPRIM VIATRIS or any other medicine in the bathroom or near a sink.

Do not leave TRIMETHOPRIM VIATRIS in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking TRIMETHOPRIM VIATRIS, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

TRIMETHOPRIM VIATRIS is a 9.5 mm white normal convex tablet marked "TM/300" on one side, "G" on the other.

Each pack contains 7 tablets.

Ingredients

The active ingredient in TRIMETHOPRIM VIATRIS is trimethoprim.

Each TRIMETHOPRIM VIATRIS tablet contains 300 mg of trimethoprim.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- povidone
- sodium starch glycollate
- purified talc
- magnesium stearate.

TRIMETHOPRIM VIATRIS tablets contain lactose and traces of sulfites and galactose.

Manufacturer

TRIMETHOPRIM VIATRIS is made in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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- AUST R 338350

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