

ALPRIM®

trimethoprim

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ALPRIM.

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 ALPRIM 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 ALPRIM is used for

ALPRIM contains the active ingredient called trimethoprim which belongs to a group of medicines called antibiotics. ALPRIM 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 ALPRIM only as directed and consult a health care professional if pain or symptoms persist.

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

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

Your doctor may have prescribed ALPRIM for another reason.

ALPRIM is available only with a doctor's prescription.

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

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

Before you take ALPRIM

When you must not take it

Do not take ALPRIM 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 ALPRIM if you have:

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

Do not take ALPRIM 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 ALPRIM 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.

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

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

ALPRIM is able to pass into breast milk. There is a possibility that the breast-fed baby may be affected. Therefore, do not take ALPRIM 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 ALPRIM.

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 ALPRIM, 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
- dapsons, 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 ALPRIM.

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

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

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

How to take ALPRIM

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 ALPRIM 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 ALPRIM, so your doctor may tell you to take a different dose.

Some people may need to take folate supplements while taking ALPRIM. 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 ALPRIM

Swallow the tablets whole with a glass of water.

When to take ALPRIM can be taken with or without food. Taking ALPRIM with food will help reduce the chance of a stomach upset.

ALPRIM tablets are best taken before bedtime.

How long to take ALPRIM for

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

For most infections, ALPRIM is usually taken for 7 days.

Do not stop taking ALPRIM, 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 ALPRIM

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 ALPRIM (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 ALPRIM.

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

You may need urgent medical attention.

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

While you are taking ALPRIM

Things you must do

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking ALPRIM.

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

If you become pregnant while taking ALPRIM, 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 ALPRIM 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 ALPRIM.

Things you must not do

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

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

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

Do not give ALPRIM 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 ALPRIM.

ALPRIM 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 ALPRIM even if you do not think

the problems are connected with the medicine or are not listed in this leaflet.

After taking ALPRIM

Storage

Keep ALPRIM 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 ALPRIM or any other medicine in the bathroom or near a sink.

Do not leave ALPRIM in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ALPRIM, 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

ALPRIM 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 ALPRIM is trimethoprim.

Each ALPRIM tablet contains 300 mg of trimethoprim.

The tablets also contain the following inactive ingredients:

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

ALPRIM tablets contain lactose and traces of sulfites and galactose.

Manufacturer

ALPRIM 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

Australian Registration Number:

ALPRIM 300 mg - AUST R 63518

This leaflet was prepared in December 2023.

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