ALPRIM®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking ALPRIM?

ALPRIM contains the active ingredient trimethoprim. ALPRIM is used to treat urinary tract infections caused by bacteria.
For more information, see Section 1. Why am I taking ALPRIM? in the full CMI.

2. What should I know before I take ALPRIM?

Do not take if you have ever had an allergic reaction to trimethoprim or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I take ALPRIM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALPRIM and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take ALPRIM?

- For adults and children over 12 years, the usual dose is one tablet daily. Elderly patients may need smaller doses.
- For children 6 to 12 years, the usual dose is half a tablet daily.

More instructions can be found in Section 4. How do I take ALPRIM? in the full CMI.

5. What should I know while taking ALPRIM?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ALPRIM. • Immediately stop taking ALPRIM if a skin rash or any other allergic reaction occurs.

Things you should not do	• Do not take any other medicines while you are taking ALPRIM without first telling your doctor. • Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	• Do not drive or operate machinery or tools until you know how ALPRIM affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your tablets in the original container until it is time to take them. • Keep ALPRIM below 30°C and protect from light.

For more information, see Section 5. What should I know while taking ALPRIM? in the full CMI.

6. Are there any side effects?

Speak to your doctor or pharmacist if you have any of these less serious side effects: nausea (feeling sick), vomiting, diarrhoea, sore tongue, stomach upset,

dizziness, fainting, ringing, hissing, whistling, buzzing, or persisting noise in the ears, joint or muscle pain, nosebleeds, urticaria, skin rashes.

Call your doctor straight away , or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects: any type of skin rash which includes redness and itching, unusual bruising or bleeding, tiredness which may occur with headache, weight loss and 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.

This is not a complete list of all possible side effects. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ALPRIM®

Active ingredient(s): *trimethoprim*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ALPRIM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ALPRIM.**

Where to find information in this leaflet:

1. Why am I taking ALPRIM?
2. What should I know before I take ALPRIM?
3. What if I am taking other medicines?
4. How do I take ALPRIM?
5. What should I know while taking ALPRIM?
6. Are there any side effects?
7. Product details

1. Why am I taking ALPRIM?

ALPRIM contains the active ingredient trimethoprim. ALPRIM is an antibiotic.

ALPRIM is used to treat urinary tract infections caused by bacteria. It works by stopping the growth of bacteria that are causing your infection.

Take 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.

2. What should I know before I take ALPRIM?

Warnings

Do not take ALPRIM if:

- You are allergic to trimethoprim, any other antibiotics, or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can take this medicine.

  Some of the symptoms of an allergic reaction to ALPRIM may include red, itchy skin rashes, difficulty in breathing, swelling of the face, lips or throat or faintness.

- It has passed the expiry date (EXP) printed on the pack.
- The packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you:

- are allergic to any other medicines or any foods, dyes or preservatives.
- have or have had, any medical conditions, especially the following:
  - folate deficiency
  - kidney problems
  - liver problems
  - porphyria
  - any type of blood disorder
  - take any medicines for any other condition

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend 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 breast-feeding or plan to breastfeed.**

Paediatric use

- ALPRIM should not be administered to premature babies or infants under 4 months of age.
- ALPRIM is not recommended for use in children under the age of 6 years.
- The safety and effectiveness of ALPRIM in children under the age of 6 years has not been established.

Elderly use

If you are elderly you may be more susceptible to this medicine. Your doctor may prescribe you a lower dose.

3. What if I am taking other medicines?

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

Some medicines may be affected by ALPRIM, or may affect how 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 heartbeat
- procainamide, a medicine used to correct an irregular heartbeat or to slow an overactive heartbeat
- zidovudine, zalcitabine or lamivudine, medicines used for certain viral infections
- dapsone, a medicine used for leprosy or dermatitis herpetiformis
- rifampicin, an antibiotic
- ciclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system
- folate antagonists and anticonvulsants
- repaglinide, used to treat diabetes
- diuretics (also known as fluid or water tablets), medicines that are used to increase the urine production
- bone marrow depressants
- 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

The above medicines may either reduce the effectiveness of ALPRIM, reduce its own effectiveness and/or react with ALPRIM resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALPRIM.

4. How do I 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

- **Adults and children over 12 years:**

  The usual dose is 1 tablet daily. Elderly patients and people with kidney problems may need smaller doses.

- **Children 6-12 years:**

  The usual dose is ½ 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.

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.

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

When to take ALPRIM

- ALPRIM tablets are best taken before bedtime.
- **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

ALPRIM should be taken regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and then go back to taking it as you would normally.

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

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 unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you have taken too much ALPRIM

If you think that you have taken too much ALPRIM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**Australia telephone 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Also report any other medicine or alcohol which has been taken.

If you take too much ALPRIM you may have the following symptoms: nausea, vomiting, dizziness, headaches, confusion, and mental depression.

5. What should I know while taking ALPRIM?

Things you should do

- **Immediately stop taking ALPRIM if a skin rash or any other allergic reaction occurs.**
- Take this medicine exactly as directed or as your doctor has prescribed.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking ALPRIM.
- If your symptoms do not improve within a few days, or if they become worse, tell your doctor.
- Always discuss with your doctor any problems or difficulties during or after taking ALPRIM.
- **Remind any doctor, dentist or pharmacist you visit that you are taking ALPRIM**.

If you have been 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.

Call your doctor straight away:

- If you become pregnant while taking ALPRIM, tell your doctor immediately.

Always discuss with your doctor any problems or difficulties during or after taking ALPRIM.

Things you should not do

- Do not take any other medicines while you are taking ALPRIM without first telling your doctor.
- Do not take ALPRIM to treat any other conditions unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Elderly use

Patients and their carers should be told how to recognise signs of blood disorders and advised to seek immediate medical attention if symptoms such as fever, sore throat, rash, mouth ulcers, area of bleeding within the skin causing a reddish-purple discoloration, bruising or bleeding develop while taking ALPRIM. These may be signs of a blood disorder.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALPRIM affects you.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it.
- Keep ALPRIM below 30°C and protect from light.

Do not take ALPRIM if the tablets do not look quite right.

Store ALPRIM in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take ALPRIM after the expiry date printed on the pack.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
• upper abdominal pain • headache • nausea (feeling sick), vomiting • diarrhoea • inflamed or sore tongue • stomach upset • cough • difficulty sleeping • dizziness, sleepiness, drowsiness • fainting • ringing, hissing, whistling, buzzing, or persisting noise in the ears • joint or muscle pain	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• nosebleeds	

Serious side effects

Serious side effects	What to do
• 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 • depression, hallucinations, confusion, nervousness, feeling anxious • signs of an allergic reaction such as itching or hives; swelling of the face, mouth, throat,	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath • Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) • blurred vision, redness of the eye, eye pain, increased sensitivity to light, uveitis (eye inflammation).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ALPRIM contains

Active ingredient **(main ingredient)**	Trimethoprim
Other ingredients **(inactive ingredients)**	Lactose monohydrate Povidone Sodium starch glycollate Purified talc Magnesium stearate
Potential allergens	Lactose and traces of sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What ALPRIM looks like

ALPRIM 300 mg is a 9.5 mm white normal convex tablet marked "TM/300" on one side, "G" on the other (AUST R 63518).

Each pack contains 7 tablets.

Who distributes ALPRIM

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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