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 using TRIPRIM?

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

2. What should I know before I use TRIPRIM?

Do not use 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 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 use TRIPRIM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRIPRIM 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 use TRIPRIM?

- Adults and children over 12 years: The usual dose is 1 tablet daily. Elderly patients may need smaller doses.
- Children 6-12 years: The usual dose is ½ tablet daily.

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

5. What should I know while using TRIPRIM?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using TRIPRIM. Immediately stop taking TRIPRIM 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 TRIPRIM without first telling your doctor. Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours. 	
Driving or using machines	Do not drive or operate machinery or tools until you know how TRIPRIM affects you.	
Drinking alcohol	Tell your doctor if you drink alcohol.	
Looking after your medicine	 Keep your tablets in the bottle they were provided in until it is time to take them. Keep TRIPRIM below 30°C and protect from light. 	

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

Common side effects include 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.

Serious side effects include 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.

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.

TRIPRIM

Active ingredient(s): *Trimethoprim*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using TRIPRIM?

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

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

2. What should I know before I use TRIPRIM?

Warnings

Do not use TRIPRIM if:

- You are allergic to trimethoprim, any other antibiotics, or any of the ingredients listed at the end of this leaflet.
- It passed the expiry date (EXP.) printed on the pack.
- The packaging is torn or shows signs of tampering.

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

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

Check with your doctor if you:

- Are allergic to any other medicines or any foods, dyes or preservatives.
- Are pregnant or intend to become pregnant.
- are breast-feeding or intend to breastfeed.
- Have or have had kidney or liver problems.
- Have or have had any type of blood disorder.
- Have or have had porphyria.
 Have or have had folate deficiency.
- Take any medicines for any other condition.

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 <u>6</u>. <u>Are there any side effects?</u>

Pregnancy and breastfeeding

TRIPRIM 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 TRIPRIM during pregnancy.

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

Paediatric Use

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

Elderly Use

- Care should be exercised in treating elderly. Elderly people may be more susceptible, and a lower dose may be advisable.
- Patients and their carers should be told how to recognize signs of blood disorders and advised to seek immediate medical attention if symptoms such as fever, sore throat, rash, mouth ulcers, purpura, bruising or bleeding develop.

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 of these medicines may interfere with TRIPRIM.

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 seizures
- digoxin, medicines used to treat heart conditions

- -procainamide, a medicine used to correct an irregular heartbeat or to slow an overactive heartbeat
- zidovudine, zalcitabine, lamivudine, medicines used to treat AIDS
- dapsone, a medicine used for leprosy or dermatitis

herpetiformis

- rifampicin, an antibiotic
- ciclosporin, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- -certain blood pressure medications that can increase potassium levels in the blood
- Folate antagonists and anticonvulsants
- repaglinide, used to treat diabetes
- diuretics, 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 TRIPRIM, reduce its own effectiveness and/or react with TRIPRIM 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 TRIPRIM.

Some medicines may interfere with TRIPRIM and affect how it works.

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

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

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

4. How do I use TRIPRIM?

How much to take

• Adults and children over 12 years:

The usual dose is 1 tablet daily.
Elderly patients may need smaller doses.

• Children 6-12 years:

The usual dose is ½ tablet daily.

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

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

Follow the instructions provided when TRIPRIM was prescribed, including the number of days it should be taken.

For most infections, TRIPRIM is only taken for 7 days.

Do not stop taking TRIPRIM, 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.

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

Swallow the tablets with a glass of water.
TRIPRIM tablets may be taken with or without food.
Taking TRIPRIM with food will lessen the chance of a stomach upset.

When to take TRIPRIM

Take your TRIPRIM tablets before bedtime.

If you forget to use TRIPRIM

TRIPRIM should be used 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 use too much TRIPRIM

If you think that you have used too much TRIPRIM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 TRIPRIM you may have the following symptoms: nausea, vomiting, dizziness, headaches, confusion, and mental depression.

5. What should I know while using TRIPRIM?

Things you should do

- Immediately stop taking TRIPRIM if a skin rash or any other allergic reaction occurs.
- Use 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 TRIPRIM.
- If your symptoms do not improve within a few days or if they become worse, tell your doctor
- Your doctor needs to check your progress and see whether you need to stop taking TRIPRIM

If you have been taking TRIPRIM for a long time, visit your doctor regularly so they can check on your progress.

You may need to have regular blood tests.

Call your doctor straight away if you:

- If you become pregnant while taking TRIPRIM, tell your doctor immediately.
- If symptoms of your infection do not improve within a few days or if they become worse, see your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are using TRIPRIM.

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

Things you should not do

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

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the bottle they were provided in until it is time to take them.
- Keep TRIPRIM below 30°C and protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

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

Store it 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 floor is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

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 about side effects.

Less serious side effects

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

Serious side effects

 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. signs of an allergic reaction such as itching or hives; swelling of 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
the face, mouth, throat, lips or tongue which may cause	•	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. signs of an allergic reaction such as itching or hives; swelling of the face, mouth, throat, lips or	or go straight to the Emergency Department at your nearest hospital if you notice any of these serious

difficulty in swallowing or breathing; wheezing or shortness of breath.

• depression, hallucinations, confusion, nervousness, feeling anxious.

• 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 TRIPRIM 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 TRIPRIM contains

Active ingredient	Trimethoprim
(main ingredient)	
Other ingredients	Starch-pregelatinised maize
(inactive ingredients)	Sodium starch glycollate
	Magnesium stearate

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

TRIPRIM does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What TRIPRIM looks like

TRIPRIM tablets (oral) are **300 mg**, white, biconvex, round tablet embossed 'TRIPRIM' and scored on the upper face. Bottom face plain. Supplied in glass bottles of 7 tablets. (Aust R 11009).

Who distributes TRIPRIM

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
www.arrotex.com.au

This leaflet was prepared in September 2024.