

RESPRIM® & RESPRIM FORTE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking RESPRIM?

RESPRIM contains the active ingredients trimethoprim and sulfamethoxazole. RESPRIM is used to treat infections in different parts of the body caused by bacteria.

For more information, see Section [1. Why am I taking RESPRIM?](#) in the full CMI.

2. What should I know before I take RESPRIM?

Do not take if you have ever had an allergic reaction to trimethoprim or sulfamethoxazole, or any other sulfonamide (sulfur) antibiotic 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 take RESPRIM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RESPRIM 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 RESPRIM?

- The dose and length of time you have to take RESPRIM will depend on the type of infection you have.
- Your doctor will tell you how much RESPRIM to take each day.

More instructions can be found in Section [4. How do I take RESPRIM?](#) in the full CMI.

5. What should I know while taking RESPRIM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking RESPRIM.• Tell your doctor if, for any reason, you have
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	<p>not taken your medicine exactly as prescribed.</p> <ul style="list-style-type: none"> ● Tell your doctor or pharmacist immediately if you get severe diarrhoea, even if it occurs several weeks after stopping RESPRIM. ● If you become pregnant while taking RESPRIM, tell your doctor.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop taking RESPRIM or change the dose without first checking with your doctor. ● Do not give your medicine to anyone else, even if they have the same condition as you. ● Do not take RESPRIM to treat any other complaints unless your doctor tells you to.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how RESPRIM affects you.

<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Tell your doctor if you drink alcohol. They may suggest you avoid alcohol while being treated with RESPRIM.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep your tablets in a cool dry place where the temperature stays below 30°C. ● Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while taking RESPRIM?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: nausea (with or without vomiting), abdominal or stomach discomfort, oral or vaginal thrush. **Serious side effects:** severe or watery diarrhoea, jaundice (yellowing of the eyes or skin), renal stones, increased or decreased urine production and discolouration, depression, imagined sensations, weakness, increased sensitivity to light, any type of skin rash, peeling of the skin, severe itching or hives, unsteadiness, eye inflammation, swelling of the face and throat, shortness of breath or lumps in the neck. **This is not a complete list of 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.

RESPRIM® & RESPRIM FORTE®

Active ingredient(s): *trimethoprim and sulfamethoxazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking RESPRIM. **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 RESPRIM.**

Where to find information in this leaflet:

- [1. Why am I taking RESPRIM?](#)
- [2. What should I know before I take RESPRIM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take RESPRIM?](#)
- [5. What should I know while taking RESPRIM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking RESPRIM?

RESPRIM contains the active ingredients trimethoprim and sulfamethoxazole , also known as co-trimoxazole. RESPRIM belongs to a group of medicines called antibiotics. There are many different types of medicines used to treat bacterial infections. Sulfamethoxazole in RESPRIM belongs

to a group of medicines known as sulfonamides. Trimethoprim belongs to a group of medicines known as the benzylpyrimidines.

RESPRIM is used to treat infections in different parts of the body caused by bacteria.

RESPRIM works by stopping the growth of the bacteria that is causing your infection.

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

RESPRIM has been prescribed for your current infection. Another infection later on may require a different medicine.

Your doctor may have prescribed RESPRIM for another reason. **Ask your doctor if you have any questions about why RESPRIM has been prescribed for you.**

2. What should I know before I take RESPRIM?

Warnings

Do not take RESPRIM if:

- you are allergic to trimethoprim, sulfamethoxazole or any other sulfonamide (sulfur) antibiotic, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing
- rash, itching or hives, peeling of the skin.

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

- you have severe liver or kidney disease, any blood disorder or megaloblastic anaemia
- the child you are treating is under 3 months of age
- you have streptococcal pharyngitis
- you are taking dofetilide, a medicine used to treat irregular heartbeats
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- **are allergic to:**
 - diuretics (fluid tablets)
 - medicines used to treat diabetes
 - medicines for an overactive thyroid.

You may have an increased chance of being allergic to RESPRIM if you are allergic to these medicines.

- **have any medical conditions, especially the following:**
 - any type of blood disorder (including porphyria and glucose-6-phosphate dehydrogenase deficiency)
 - liver or kidney disease
 - a hereditary disease called phenylketonuria

- epilepsy (fits or convulsions)
 - asthma
 - allergic disorders
 - rheumatoid arthritis
 - urinary obstruction
 - folic acid deficiency.
- **are allergic to any other medicines, foods, dyes or preservatives.**

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

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

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

If RESPRIM is taken during pregnancy, it may harm the baby. Your doctor will discuss the risks and benefits of taking RESPRIM during pregnancy.

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

RESPRIM passes into breast milk. Your doctor will discuss the risks and benefits of taking RESPRIM when breastfeeding.

Use in very young children

RESPRIM should not be given to children under 12 years of age. Alternative dosage form of trimethoprim and sulfamethoxazole is available from other brands for children from 3 months to 12 years of age.

Use in people over 65 years

People over 65 years are at more risk of severe side effects when taking RESPRIM. The risk is greater if you have kidney or liver disease or are taking other medicines, such as diuretics.

Use in people with HIV infection

People with HIV infection may not respond to RESPRIM in the same way as people without HIV. People with HIV infection have been reported to get more side effects while being treated with RESPRIM than people without HIV.

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 interfere with RESPRIM and affect how it works. These include:

- medicines used to treat diabetes such as repaglinide, rosiglitazone, pioglitazone, glibenclamide, gliclazide, glipizide, chlorpropamide and tolbutamide
- diuretics (fluid tablets)
- phenytoin, a medicine used to treat epilepsy
- pyrimethamine, a medicine used to prevent malaria
- other medicines used to treat infections such as rifampicin, dapsona and polymyxin
- zidovudine, a medicine used to treat HIV infection
- ciclosporin, a medicine used to prevent organ transplant rejections or to treat certain problems with the immune system
- warfarin, acenocoumarol, phenprocoumon, medicines used to thin the blood
- medicines used to treat some heart conditions such as digoxin and amiodarone
- amantadine, a medicine commonly used to treat the influenza virus and Parkinson's disease
- memantine, a medicine used to treat Parkinson's disease
- lamivudine, an antiretroviral medicine used to treat HIV/AIDS
- urinary acidifiers (for kidney conditions)
- oral contraceptives ('the pill')
- sulfinpyrazone, a medicine used to treat gout
- salicylates, medicines to treat conditions such as psoriasis or warts
- medicines used to treat cancer such as paclitaxel, mercaptopurine and methotrexate

- clozapine, a medicine used to treat schizophrenia
- medicines used to treat overactive thyroid conditions
- medicines used to treat depression such as imipramine, clomipramine, amitriptyline, dosulepin (dothiepin), doxepin, nortriptyline and trimipramine
- immunosuppressant medicines such as azathioprine and methotrexate
- medicines used to treat high blood pressure as well as a variety of heart and kidney conditions such as captopril, enalapril, lisinopril, fosinopril, perindopril, quinapril, ramipril, trandolapril, valsartan, telmisartan, irbesartan, candesartan, eprosartan, losartan, dofetilide and olmesartan.

These medicines may be affected by RESPRIM or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking RESPRIM.

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

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

4. How do I take RESPRIM?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

- The dose and length of time you have to take RESPRIM will depend on the type of infection you have.
- Your doctor will tell you how much RESPRIM to take each day.
- **Take RESPRIM exactly as your doctor has prescribed.**
- The usual dose for adults and children over 12 years is one RESPRIM FORTE tablet (or two RESPRIM tablets) twice a day.

How to take RESPRIM

- Swallow the tablets whole with a glass of water.
- Take RESPRIM after food. This will lessen the chance of a stomach upset.

How long to take RESPRIM for

- **Continue taking RESPRIM for as long as your doctor recommends.**

- **Do not stop taking RESPRIM, 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 your symptoms do not improve within a few days, or if they become worse, let your doctor know.

If you forget to take RESPRIM

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 medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

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

If you take too much RESPRIM

If you think that you or anyone else has taken too much RESPRIM, urgent medical attention may be needed.

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.

If you take too much RESPRIM, you may feel sick, vomit, feel dizzy, depressed or confused or have a headache. You may also feel drowsy or become unconscious.

5. What should I know while taking RESPRIM?

Things you should do

- Before starting any new medicine, tell your doctor or pharmacist that you are taking RESPRIM.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking RESPRIM.
- If you become pregnant while taking RESPRIM, tell your doctor.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

- Tell your doctor if you feel that RESPRIM is not helping your condition.
- Drink plenty of fluids while you are taking RESPRIM. This will help to flush the medicine through your system.

- If you are taking RESPRIM for a long time, visit your doctor regularly so your progress can be checked.
Your doctor may ask you to have regular tests to check your kidneys, liver or blood.
- If you have to have any blood tests, tell your doctor that you are taking RESPRIM.
RESPRIM may affect the results of some tests.

Call your doctor or pharmacist straight away if you:

- **get severe diarrhoea, even if it occurs several weeks after stopping RESPRIM. Do not take any diarrhoea medicine without checking with your doctor.**

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Things you should not do

- Do not stop taking RESPRIM or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take RESPRIM to treat any other complaints unless your doctor tells you to.

- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining RESPRIM and alcohol can make you feel sick, vomit, or have stomach cramps, headaches and flushing. Your doctor may suggest you avoid alcohol while being treated with RESPRIM.

Things to be careful of

- Sometimes the use of this medicine allows other bacteria and fungi which are not sensitive to RESPRIM to grow. If other infections such as thrush occur while you are taking RESPRIM tell your doctor.
- Your skin may burn more easily while you are taking RESPRIM. If outdoors, wear protective clothing or use a SPF 30+ sunscreen.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

- Store below 30°C.

Keep RESPRIM 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 or 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 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> ● nausea, with or without vomiting ● diarrhoea or other abdominal (gut) or stomach discomfort ● oral thrush (white, furry sore tongue and mouth) ● vaginal thrush (sore and itchy vagina, vaginal discharge) <p>Your doctor will need to treat the thrush infection separately.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These side effects are usually not serious or long lasting.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● jaundice (yellowing of the eyes or skin) ● severe or watery diarrhoea ● any type of skin rash, peeling of the skin, severe itching or hives 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● fever, sore throat, lumps in the neck ● cough, shortness of breath ● severe persistent headache ● discolouration of urine ● renal stones ● swelling of the face and throat ● other allergic reactions ● pins and needles in the hands & feet ● loss of appetite, fits, headaches, depression, imagined sensations or nervousness ● increased or decreased urine production ● unsteadiness or dizziness ● sleeplessness, weakness, tiredness, increased sensitivity to light and stomach pains ● uveitis (eye inflammation) 	<p>These side effects are usually rare but may be serious and need urgent medical attention.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if it is not on this list.

This is not a complete list of all possible side effects. Other side effects not listed here may occur in some people.

Very rarely, people have died from complications due to certain severe skin, liver and blood reactions.

Elderly people, people with liver or kidney disease and people taking certain other medicines are more at risk of these severe reactions.

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 RESPRIM contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">● RESPRIM trimethoprim 80 mg sulfamethoxazole 400 mg● RESPRIM FORTE trimethoprim 160 mg sulfamethoxazole 800 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● povidone● docusate sodium● sodium starch glycollate● magnesium stearate
Potential allergens	sulfites

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

What RESPRIM looks like

RESPRIM is an 11 mm flat bevelled edge white tablet, marked "80|400" on one side and "R" on the other side (AUST R 17681).

RESPRIM FORTE is a 19 mm x 9 mm oblong convex white tablet, marked "160|800" on one side and "RF" on the other side (AUST R 17682).

Each blister pack contains 10 tablets.

Who distributes RESPRIM

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

This leaflet was prepared in October 2024.

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