

SEPTRIN Forte

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 SEPTRIN Forte?

SEPTRIN Forte contains the active ingredients trimethoprim and sulfamethoxazole. SEPTRIN Forte is used to treat a variety of bacterial infections, including bronchitis and infections of the ear, sinus, kidney, bladder, stomach, bowel, skin and wounds.

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

2. What should I know before I use SEPTRIN Forte?

Do not use if you have ever had an allergic reaction to trimethoprim and/ or sulfamethoxazole 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 SEPTRIN Forte?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEPTRIN Forte 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 SEPTRIN Forte?

- For adults and children over 12 years old the usual dose is one SEPTRIN Forte Tablet, twice a day.

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

5. What should I know while using SEPTRIN Forte?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SEPTRIN Forte.• It is important that you drink plenty of fluids (water) while you are taking SEPTRIN Forte.
Things you should not do	<ul style="list-style-type: none">• Do not stop using SEPTRIN Forte just because you feel better.• It is important that you take the full course of SEPTRIN Forte prescribed by your doctor. This will reduce the risk of your infection recurring.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how SEPTRIN Forte affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Alcohol may make you feel sick, vomit, or have stomach cramps, headaches and flushing.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets below 30°C. Protect from light.• Keep your SEPTRIN Forte in the container it was supplied with.

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

6. Are there any side effects?

Common side effects include nausea, vomiting, diarrhoea or other abdominal (gut) or stomach discomfort and inflammation of the mouth or tongue.

Serious side effects include any form of skin rash, severe fever, chills, sore throat, joint pains, cough or bruising, difficulty breathing or chest pains, severe, persistent diarrhoea, jaundice (yellowing of the skin), severe persistent headache, discolouration of urine.

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.

SEPTRIN Forte

Active ingredient(s): *trimethoprim and sulfamethoxazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEPTRIN Forte. **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 SEPTRIN Forte.**

Where to find information in this leaflet:

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

1. Why am I using SEPTRIN Forte?

SEPTRIN Forte contains the active ingredients **trimethoprim and sulfamethoxazole**. SEPTRIN Forte belongs to a group of medicines called "anti-infectives". They work in slightly different ways to stop the growth of bacteria causing the infection.

SEPTRIN Forte is used for the treatment of a variety of bacterial infections, including bronchitis and infections of the ear, sinus, kidney, bladder, stomach, bowel, skin and wounds.

2. What should I know before I use SEPTRIN Forte?

Warnings

Do not use SEPTRIN Forte if:

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

Do not use SEPTRIN Forte to treat any other conditions unless advised by your doctor.

Do not give SEPTRIN Forte to anyone else, even if their symptoms seem similar to yours.

Check with your doctor if you:

- Are allergic to trimethoprim, sulfamethoxazole or any other ingredient listed at the end of this information.
- Are allergic to any other sulphonamide type antibiotics, any diuretics (medicines that increase the volume of your urine), or medicines for diabetes or an overactive thyroid gland.
- Have ever had any type of liver, kidney or bladder complaint or disease (eg. hepatitis).
- Have ever had any type of blood disorder (including porphyria and glucose-6-phosphate dehydrogenase deficiency).
- Have asthma or an allergic disorder.
- Have a folic acid vitamin deficiency.
- Have phenylketonuria.
- Suffer from alcoholism.
- Suffer from rheumatoid arthritis.
- Are being treated for epilepsy (fits).
- Take any medicines for any other condition.
- Have been diagnosed with AIDS.
People with AIDS may not tolerate or respond to SEPTRIN in the same manner as someone who does not have AIDS. There may be an increase in the number and severity of side effects.

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.

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

Pediatric Use

SEPTRIN Forte should not be used in premature babies nor during the first six weeks of life. It should probably not be given to infants less than 3 months of age.

Use in the Elderly

The use of SEPTRIN Forte in elderly patients, particularly those with a liver or kidney disease or those taking certain other medicines such as diuretics, carries an increased risk of severe adverse reactions.

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 SEPTRIN Forte and affect how it works.

Below medicines may be affected by SEPTRIN Forte 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.

- Any malaria medicines (eg. pyrimethamine).
- Any diabetes medicines such as repaglinide, rosiglitazone, pioglitazone, glibenclamide, gliclazide, glipizide, chlorpropamide and tolbutamide.
- Any diuretics (diuretics).
- Any epilepsy (fits) medicines (eg. phenytoin, primidone and some barbiturates).
- Any medicines used to treat infections such as rifampicin, dapsone and polymyxin.
- Zidovudine, a medicine 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.

- Procainamide.

Your doctor will have a complete list of the medicines that may cause problems when taken with SEPTRIN Forte.

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

4. How do I use SEPTRIN Forte?

How much to take

- For adults and children over 12 years old the usual dose is one SEPTRIN Forte Tablet, twice a day.
- Follow the instructions provided when SEPTRIN Forte was prescribed, including the number of days it should be taken.

Depending on the type of infection, and your overall health, your doctor may prescribe a different dose of SEPTRIN Forte.

How to take SEPTRIN Forte

SEPTRIN Forte Tablets should be taken with a glass of water.

Do not crush or chew the tablets.

If you forget to use SEPTRIN Forte

SEPTRIN Forte should be used regularly at the same time each day.

If you miss your dose at the usual time, 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 dose that you have missed as soon as you remember, then go back to your normal schedule.

If you have forgotten to take more than one dose, contact your doctor or pharmacist.

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

If you use too much SEPTRIN Forte

If you think that you have used too much SEPTRIN Forte, 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.

If you take too much SEPTRIN Forte you may have the following symptoms: nausea, vomiting, dizziness, headache, depression and confusion. It is also possible that you will feel drowsy and you may lose consciousness.

5. What should I know while using SEPTRIN Forte?

Things you should do

It is important that you drink plenty of fluids (water) while you are taking SEPTRIN Forte.

Tell your doctor that you are taking SEPTRIN Forte before you have any blood tests.

If you are taking SEPTRIN Forte over a long period, or you have kidney problems, your doctor may ask you to undergo regular blood and urine tests.

Drink plenty of fluids while you are taking SEPTRIN Forte. This will help to flush the medicine through your system.

Call your doctor straight away if you:

- If you become pregnant while taking SEPTRIN Forte
- If you feel the tablets is not helping your condition
- You get severe diarrhoea, even if it occurs several weeks after stopping SEPTRIN Forte

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.

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

If you are taking SEPTRIN Forte for a long time, visit your doctor regularly so your progress can be checked.

Things you must not do

- Do not stop using SEPTRIN Forte just because you feel better.
- Do not stop taking SEPTRIN Forte 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 SEPTRIN Forte 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.

It is important that you take the full course of SEPTRIN Forte prescribed by your doctor. This will reduce the risk of your infection recurring.

Things to be careful of

Sometimes use of this medicine allows other bacteria and fungi which are not sensitive to SEPTRIN Forte to grow. If

other infections such as thrush occur while you are taking SEPTRIN Forte tell your doctor.

Your skin may burn more easily while you are taking SEPTRIN Forte. If outdoors, wear protective clothing or use a SPF 30+ sunscreen.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep your tablets below 30°C. Protect from light.
- Keep your SEPTRIN Forte in the container it was supplied with.

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

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 may affect this medicine.

Keep it where young children cannot reach it.

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
<ul style="list-style-type: none">• Nausea.• Vomiting.• Diarrhoea or other abdominal (gut) or stomach discomfort.• Inflammation of the mouth or tongue.• Oral thrush (white, furry sore tongue and mouth).	Speak to your doctor if you have any of these less serious side effects and they worry you.

<ul style="list-style-type: none"> • Vaginal thrush (sore and itchy vagina, vaginal discharge). 	Your doctor will need to treat the thrush infection separately.
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Any form of skin rash, peeling of the skin, severe itching or hives The rash may indicate that you are allergic to SEPTRIN Forte. In very rare circumstances, patients have died from complications that may arise from certain severe allergic reactions. • Severe fever, chills, sore throat, lumps in the neck joint pains, cough or bruising. • Difficulty breathing or chest pains. • Severe, persistent diarrhoea. This is particularly important if there is any blood or mucus present. It is possible for this reaction to only become apparent several weeks after taking SEPTRIN Forte. • Jaundice (yellowing of the skin), which is related to the function of your liver. • Severe persistent headache. • Discolouration of urine. • renal stones • swelling of the face and 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.

Other rare side effects	What to do
<ul style="list-style-type: none"> • Various other allergic side effects, • Pins and needles in the hands and feet. • Ringing in the ears. • Diarrhoea. • Loss of appetite. • Kidney damage. • Fits. • Headaches, depression, imagined sensations (hallucinations). • Nervousness. • An increase or decrease in urine production. • Unsteadiness. • Dizziness, sleeplessness, weakness, tiredness. • Increased sensitivity to light. • Respiratory toxicity (Acute Respiratory Distress Syndrome). • Stomach pains. 	Contact your doctor as soon as possible if you have any of these rare side effects

<ul style="list-style-type: none"> • Uveitis (eye inflammation) 	
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Ask your doctor or pharmacist if you don't understand anything in this list.

Various effects on the blood, particularly in the elderly, have been attributed to the use of SEPTRIN Forte. In very rare circumstances, patients have died from some of these effects.

Having a blood test may be able to detect these effects.

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.

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 SEPTRIN Forte contains

Active ingredient (main ingredient)	160 mg of trimethoprim 800 mg sulfamethoxazole
Other ingredients (inactive ingredients)	povidone docusate sodium sodium starch glycolate magnesium stearate

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

What SEPTRIN Forte looks like

SEPTRIN Forte Tablets are white, elliptical, biconvex, and embossed "SEPTRIN FORTE" on the upper face and the bottom face is plain and scored along the shorter axis. They are supplied in blister packs of 10 tablets. (Aust R 10998).

Who distributes SEPTRIN Forte

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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