

SEPTRIN Forte & SEPTRIN Sugar-Free Paediatric Suspension

trimethoprim and sulfamethoxazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SEPTRIN. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

Taking any medicine involves some risk. Your doctor has weighed the risks of you using SEPTRIN against the benefits they expect it will have for you.

If you have any concerns about taking SEPTRIN, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may want to read it again.

What SEPTRIN is used for

SEPTRIN 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.

Trimethoprim and sulfamethoxazole (the active ingredients in SEPTRIN) belong to a group of medicines called "anti-infectives". They work in slightly different ways to stop the growth of bacteria causing the infection.

If you have any questions about why you are taking SEPTRIN, ask your doctor or pharmacist.

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

SEPTRIN is only available with a doctor's prescription.

Before taking it

When you must not take it

Do not use SEPTRIN if you have an allergy to:

- trimethoprim
- Sulfamethoxazole
- Any of the ingredients listed at the end of this leaflet

Do not take SEPTRIN after the expiry date printed on the pack or bottle.

SEPTRIN may have no effect if you take it after the expiry date.

Do not take SEPTRIN if the packaging appears to have been tampered with.

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

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

Before you start to use it

You must tell your doctor if:

You are allergic to:

- trimethoprim, sulfamethoxazole or any other ingredient listed at the end of this information.
- any other sulphonamide type antibiotics, any diuretics (medicines that increase the volume of your urine), or medicines for diabetes or an overactive thyroid gland.

You are pregnant or breastfeeding or become pregnant, while taking SEPTRIN.

You have ever had any type of liver, kidney or bladder complaint or disease (eg. hepatitis).

You have ever had any type of blood disorder (including porphyria and glucose-6-phosphate dehydrogenase deficiency).

You have asthma or an allergic disorder.

You have a folic acid vitamin deficiency.

You have phenylketonuria.

You suffer from alcoholism.

You suffer from rheumatoid arthritis.

You are being treated for epilepsy (fits).

You 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.

You are taking any medicines, including:

- Any malaria medicines (eg. pyrimethamine)
- Any diabetes medicines
- Any diuretics
- Any epilepsy (fits) medicines (eg. phenytoin, primidone and some barbiturates)
- Rifampicin, methotrexate, cyclosporin, warfarin, digoxin, procainamide or amantadine

You are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

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

SEPTRIN and very young children

SEPTRIN should not be used in premature babies or in children younger than 2 months old.

SEPTRIN and the elderly

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

How to take it

How much to take

Take SEPTRIN as directed by your doctor or pharmacist.

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

The dose of SEPTRIN Sugar-Free Paediatric Suspension for children under 12 years old depends on your child's weight and age.

Your doctor or pharmacist will be able to tell you how much your child should be given.

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

Always take the full course of SEPTRIN prescribed by your doctor.

How to take it

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

Do not crush or chew the tablets.

SEPTRIN Sugar-Free Paediatric Suspension should be shaken before use. The correct amount of the suspension

should be measured before being given by mouth.

If you forget to take it

If it is almost time for your next dose, skip the dose that you have missed and take your next dose when you are supposed 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 that you have missed.

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

If you take too much (overdose)

Immediately contact your doctor or Poisons Information Centre for advice, or go to Casualty at your nearest hospital, if you think that you or anyone else may have taken too much SEPTRIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If too much SEPTRIN has been taken signs and symptoms may include nausea, vomiting, dizziness, headache, depression and confusion. It is also possible that you will feel drowsy and you may lose consciousness.

While you are taking it

Things you must do

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

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

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

Your doctor or pharmacist will be able to tell you whether there are any other special instructions while you are taking SEPTRIN.

Things you must not do

Do not stop taking SEPTRIN just because you feel better.

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

Your doctor will advise you when to stop taking SEPTRIN.

If you are unsure whether you should stop taking SEPTRIN, talk to your doctor or pharmacist.

Side Effects

Stop taking SEPTRIN and tell your doctor immediately if you notice, or experience, any of the following (you may need urgent medical attention):

- Any form of skin rash. The rash may indicate that you are allergic to SEPTRIN. In very rare

circumstances, patients have died from complications that may arise from certain severe allergic reactions. Your doctor will know what action to take if you develop a severe reaction.

- Severe fever, chills, sore throat, 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.
- Jaundice (yellowing of the skin), which is related to the function of your liver.

SEPTRIN may also cause more common side effects such as nausea, vomiting and inflammation of the mouth or tongue.

Other rare side effects include 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 and stomach pains.

If you experience any of these side effects, please contact your doctor as soon as possible.

Various effects on the blood, particularly in the elderly, have been attributed to the use of SEPTRIN. 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 as soon as possible if you think you are experiencing any side effects from taking SEPTRIN.

After using it

If your doctor advises you to stop taking SEPTRIN, ask your pharmacist what to do with any SEPTRIN that you may have left.

Storage

Keep your tablets in a cool dry place where the temperature stays below 30°C. Protect the tablets from light.

Keep SEPTRIN Sugar-Free Suspension in a cool dry place where the temperature stays below 30°C. Protect the suspension from light.

Keep your SEPTRIN in the container it was supplied with.

Do not store SEPTRIN in the bathroom or near a sink.

Heat and dampness may affect this medicine.

Do not leave SEPTRIN in the car on hot days.

Keep SEPTRIN and all other medicines, where children cannot reach them.

Product description

What it looks like

SEPTRIN Forte Tablets are elongated, white, scored and marked "SEPTRIN FORTE". They are supplied in blister packs of 10 tablets.

SEPTRIN Sugar-Free Suspension is a thick, pink cherry flavoured liquid in a 100 mL bottle.

Ingredients

Each SEPTRIN Forte Tablet contains 160 mg of trimethoprim and 800 mg sulfamethoxazole.

The tablets also contain:

- povidone
- docusate sodium
- sodium starch glycolate
- magnesium stearate

Every 5 mL of Septrin Sugar-Free Paediatric Suspension contains 40 mg trimethoprim and 200 mg sulfamethoxazole.

The suspension also contains:

- carmellose sodium
- saccharin sodium
- cellulose-dispersible
- glycerol
- polysorbate 80
- citric acid - anhydrous
- sorbitol
- ethanol
- water
- sunset yellow FCF (CI 5985)
- allura red AC (CI 16035)
- Cherry Flavour Artif F1242 (PI 286)
- methyl hydroxybenzoate
- sodium benzoate

The Australian Registration numbers are:

Seprin Forte Tablets: AUST R 10998

Seprin Sugar-Free Paediatric Suspension: AUST R 11000

Supplier

Arrow Pharma Pty
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