

SEPTRIN Sugar-Free Paediatric Suspension

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 ?

SEPTRIN contains the active ingredients trimethoprim and sulfamethoxazole. 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.

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

2. What should I know before I use SEPTRIN?

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

3. What if I am taking other medicines?

Some medicines may interfere with SEPTRIN 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 ?

- Take SEPTRIN as directed by your doctor or pharmacist
- Follow the instructions provided and use SEPTRIN until your doctor tells you to stop.

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

5. What should I know while using SEPTRIN ?

Things you should do	<ul style="list-style-type: none">• 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly 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.
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 affects you• Your skin may burn more easily while you are taking SEPTRIN. If outdoors, wear protective clothing or use a SPF 30+ sunscreen.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep SEPTRIN Sugar-Free Suspension in a cool dry place where the temperature stays below 25°C.• Protect the suspension from light.• Keep your SEPTRIN in the container it was supplied with• Heat and dampness may affect this medicine• Keep it where young children cannot reach it.

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

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

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 Sugar-Free Paediatric Suspension

Active ingredient(s): *trimethoprim and sulfamethoxazole*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using SEPTRIN ?

SEPTRIN contains the active ingredients trimethoprim and sulfamethoxazole. 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.

2. What should I know before I use SEPTRIN ?

Warnings

Do not use SEPTRIN if:

- you are allergic to Trimethoprim, Sulfamethoxazole, any other sulfonamide (sulfur) antibiotic or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with 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.

- have any other medical conditions including:
 - Acute porphyria
 - Severe atopy
 - Any type of liver, kidney or bladder complaint or disease (e.g. hepatitis)
 - History of drug-induced immune thrombocytopenia with use of trimethoprim and/or sulphonamides
 - Documented megaloblastic anemia due to folate deficiency or blood dyscrasia
 - Any type of blood disorder (including porphyria and glucose-6-phosphate dehydrogenase deficiency)
 - At risk of hyperkalaemia and hyponatraemia
 - Haemophagocytic lymphohistiocytosis
 - Asthma or an allergic disorder
 - Underweight or malnourished
 - Phenylketonuria
 - Gastrointestinal tract infection
 - Alcoholism
 - Suffer from rheumatoid arthritis
 - 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.

If you become pregnant, while taking SEPTRIN, tell your doctor straight away. Administration of SEPTRIN should be avoided in pregnancy especially in the first trimester, unless clearly necessary as Trimethoprim and sulfamethoxazole cross the placenta and their safety in human pregnancy has not been established.

Administration of SEPTRIN should be avoided in lactating mothers where the mother or infant has, or is at particular risk of developing, hyperbilirubinaemia

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

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.

If you are taking any medicines, including:

- 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
- Cyclosporin, 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
- Folinic acid
- Medicines that can cause hyperkalaemia, for example ACE inhibitors, angiotensin receptor blockers and potassium-sparing diuretics such as spironolactone.
- Sulphonylurea hypoglycemic agents.
- Trimethoprim is an inhibitor of cytochrome P450 2C8 enzyme and may interact with other drugs that are primarily metabolized by the 2C8 isoform. Sulfamethoxazole is an inhibitor of cytochrome P450

2C9 and may interact with other drugs that are primarily metabolized by the 2C9 isoform.

These medicines may be affected by SEPTRIN 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.

If 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 infants during the first 2 months of life.

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 such as diuretics (thiazides), carries an increased risk of severe adverse reactions.

In addition, the appearance of skin rashes, particularly in elderly patients, warrants the immediate removal of treatment.

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 .

4. How do I use SEPTRIN ?

How much to take

- Take SEPTRIN as directed by your doctor or pharmacist
- Follow the instructions provided and use SEPTRIN until your doctor tells you to stop.

When to take SEPTRIN

- 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 SEPTRIN

- 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 use SEPTRIN

SEPTRIN should be used regularly at the same time each day. If you miss your dose at the usual time, skip the dose

that you have 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 that you have missed.

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

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

If you use too much SEPTRIN

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

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.

5. What should I know while using SEPTRIN?

Things you should 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.

If you become pregnant while taking SEPTRIN, tell your doctor.

Call your doctor straight away if you:

- get severe diarrhoea, even if it occurs several weeks after stopping SEPTRIN.

Remind any doctor, dentist or pharmacist you visit that you are using SEPTRIN. 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 using this medicine suddenly 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.

Driving or using machines

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

Sometimes use of this medicine allows other bacteria and fungi which are not sensitive to SEPTRIN grow. If other infections such as thrush occur while you are taking SEPTRIN tell your doctor.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep SEPTRIN Sugar-Free Suspension in a cool dry place where the temperature stays below 25°C.
- Protect the suspension from light.
- Keep your SEPTRIN 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 on hot days or on window sills.

Heat and dampness may affect this medicine

Keep it where young children cannot reach it.

When to discard your medicine

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

Do not take SEPTRIN:

- after the expiry date printed on the pack or bottle. The medicine may have no effect if you take it after the expiry date.
- if the packaging appears to have been tampered with.
- 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.

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.

Stop taking SEPTRIN and tell your doctor immediately if you notice, or experience, any of the following (you may need urgent 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 • Dry mouth • Vomiting • Sores • Peeling of skin • Diarrhoea or other abdominal (gut) • Stomach discomfort • Inflammation of the mouth or tongue • Weakness • Fatigue • Body aches • Insomnia • Vision troubles • Alopecia • Epistaxis • Edema • QT prolongation • Pyrosis • Gastric intolerance • Gastritis or gastroenteritis • Dyspepsia emesis • Constipation • Flatulence • Tooth and/or tongue discoloration • Kidney changes • Hematuria, urgency, and dysuria, hypoprothrombinemia • Tremor. • Monilial overgrowth is common • Oral thrush (white, furry sore tongue and mouth) • Vaginal thrush (sore and itchy vagina, vaginal discharge) • Pseudomembranous enterocolitis • pancreatitis 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects are not usually serious or long lasting.</p> <p>For thrush, your doctor will need to treat the thrush infection separately.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 (Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS)). 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. • Severe persistent headache. • Discolouration of urine. • Acute generalised exanthematous pustulosis (AGEP) • Cholestatic jaundice and hepatic necrosis may be fatal. • Haematological changes • Toxicoderma • Exfoliative dermatitis • Serum sickness • Generalized skin eruptions • Pruritus • Urticaria • Anaphylactoid reactions (sweating and collapse) • Pins and needles in the hands and feet • Ringing in the ears • Loss of appetite • Metabolism and nutrition disorders • Kidney damage • Fits • Headaches • Depression • Imagined sensations (hallucinations) 	<p>Stop taking SEPTRIN and 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"> Nervousness Increase or decrease in urine production Unsteadiness Dizziness Sleeplessness Weakness Tiredness, Increased sensitivity to light Stomach pains Fixed drug eruption Erythema multiforme Anaphylactic reaction Allergic myocarditis Erythema multiforme Toxicoderma Exfoliative dermatitis Angioedema Pyrexia Chills Hypersensitivity Vasculitis resembling Henoch-Schönlein purpura Serum sickness Serum sickness-like syndrome Generalized allergic reactions Generalized skin eruptions Fixed drug eruption Photosensitivity Conjunctival Scleral injection Pruritus Urticaria Rash Periarteritis nodosa Systemic lupus erythematosus 	

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.

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

What SEPTRIN contains

Active ingredient (main ingredient)	Every 5 mL of Septrin Sugar-Free Paediatric Suspension contains 40 mg trimethoprim and 200 mg sulfamethoxazole.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> 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
Potential allergens	contains Methyl hydroxybenzoate, Sodium benzoate and Saccharin sodium.

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

What SEPTRIN looks like

Septrin Sugar-Free Paediatric Suspension
AUST R 11000

Who distributes SEPTRIN

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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