

Laboratoires Genopharm logo

Package Leaflet: Information for the User

Seprin® 40 mg/200 mg per 5 ml Paediatric Suspension co-trimoxazole

Read all of this leaflet carefully before your child starts taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

In this leaflet:

- 1 What Seprin is and what it is used for
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1 What Seprin is and what it is used for

Seprin 40 mg/200 mg per 5 ml Paediatric Suspension (called 'Seprin' in this leaflet) is made up of two different medicines called sulfamethoxazole and trimethoprim. These medicines are sometimes given the combined name co-trimoxazole. Both belong to a group of medicines called antibiotics. They are used to treat infections caused by bacteria. Like all antibiotics, Seprin only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Seprin can be used to treat or prevent:

- lung infections (pneumonia or PCP) caused by a bacteria called *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*)
- infections caused by a bacteria called Toxoplasma (toxoplasmosis).

Seprin can be used to treat:

- bladder or urinary tract infections (water infections)
- lung infections such as bronchitis
- ear infections such as otitis media
- an infection called nocardiosis, it can affect the lungs, skin and brain.

2 Before your child takes Seprin

Your child should not take Seprin if:

- they are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of Seprin (see section 6: Further information)
- they are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet)
- they have liver or kidney problems
- they have ever had a problem with their blood
- they are less than 6 weeks old or were premature, unless it is for the treatment or prevention of PCP. In this case, babies should be at least 4 weeks old.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before they take Seprin.

Take special care with Seprin

Before your child takes Seprin, tell their doctor or pharmacist if:

- they have severe allergies or asthma

- they have ever had an allergic skin reaction such as Stevens-Johnson syndrome or Lyell's syndrome – where they would get blisters on their skin, mouth, eyes and genitals
- you have been told that your child has a rare blood problem called porphyria, which can affect the skin or nervous system
- they don't have enough folic acid (a vitamin) in their body - which can make their skin pale and make them feel tired, weak and breathless. This is known as anaemia
- they have ever had jaundice which can cause yellowing of their skin or the whites of their eyes
- they have a problem with their metabolism called phenylketonuria and are not on a special diet to help their condition
- they are underweight or malnourished
- you have been told by your child's doctor that your child has a lot of potassium in their blood.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before they take Septrin.

Taking other medicines

Please tell your child's doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Septrin can affect the way some medicines work. Also some other medicines can affect the way Septrin works.

In particular tell your child's doctor or pharmacist if your child is taking any of the following medicines:

- Diuretics (water tablets), which help increase the amount of urine produced
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea
- Ciclosporin, used after transplant operations or for the immune system
- Medicines used to thin the blood such as warfarin
- Phenytoin, used to treat epilepsy (fits)
- Medicines for diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas)
- Medicines to treat problems with the way the heart beats such as digoxin or procainamide
- Amantadine, used to treat Parkinson's disease, multiple sclerosis, flu or shingles
- Medicines to treat HIV (Human Immunodeficiency Virus), called zidovudine or lamivudine
- Medicines that can increase the amount of potassium in the blood, such as diuretics (water tablets, which help increase the amount of urine produced), steroids (like prednisolone) and digoxin
- Methotrexate, a medicine used to treat cancer or for the immune system.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before they take Septrin.

Taking Septrin with food and drink

Your child should take Septrin with some food or drink. This will stop them feeling sick (nausea) or having diarrhoea. Although it is better to take it with food, they can still take it on an empty stomach. Make sure your child drinks plenty of fluid such as water while they are taking Septrin.

Important information about some of the ingredients of Septrin 40 mg/200 mg per 5 ml

Paediatric Suspension

Septrin 40 mg/200 mg per 5 ml Paediatric Suspension contains:

- 3.25 g sorbitol in every 5 ml spoonful. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), contact your doctor before taking this medicinal product.
- A small amount of ethanol (alcohol), less than 100 mg per 5 ml spoonful.
- Methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).
- Benzoate, which may increase the risk of jaundice in newborn babies.
- Less than 1 mmol sodium (23 mg) per 5 ml, i.e. essentially 'sodium free'.

3 How to give Septrin 40 mg/200 mg per 5 ml Paediatric Suspension

Always ensure your child takes Septrin exactly as their doctor has told you. The label on the pack will tell you how much they should take and how often to take it. You should check with their doctor or pharmacist if you are not sure.

Usual Dose

The dose to be given will depend on the age of your child:

- 6 to 12 years old: two 5 ml spoonfuls in a morning and two 5 ml spoonfuls in an evening.
- 6 months to 5 years: one 5 ml spoonful in a morning and one 5 ml spoonful in an evening.
- 6 weeks to 5 months: one 2.5 ml spoonful in a morning and one 2.5 ml spoonful in an evening.
- Septrin should be taken for at least five days
- Make sure that your child finishes the course of Septrin which their doctor has prescribed.

Special Dose

The dose of Septrin and how long your child needs to take it depends on the infection they have and how bad it is. Your child's doctor may prescribe a different dose or length of course of Septrin to

- treat urinary tract (water) infections
- treat and prevent lung infections caused by the bacteria *Pneumocystis jiroveci*
- treat infections caused by the bacteria *Toxoplasma* (toxoplasmosis) or *Nocardia* (nocardiosis).

If your child takes Septrin for a long time their doctor may

- take blood to test whether the medicine is working properly
- prescribe folic acid (a vitamin) for your child to take at the same time as Septrin.

If your child takes more Septrin than they should

If your child takes more Septrin than they should, talk to their doctor or go to a hospital straight away. Take the medicine pack with you. If your child has taken too much Septrin they may:

- feel or be sick
- feel dizzy or confused.

If you forget to give your child Septrin

- If a dose is forgotten, your child should take it as soon as possible.
- A double dose should not be taken to make up for the forgotten dose.

4 Possible side effects

Like all medicines Septrin can cause side effects, although not everybody gets them. Your child may experience the following side effects with this medicine.

Stop taking Septrin and tell your doctor immediately if you have an allergic reaction. Chances of an allergic reaction is very rare (fewer than 1 in 10,000 people are affected), signs of an allergic reaction include

Allergic reactions

- Difficulty in breathing
- Fainting
- Swelling of face
- Swelling of mouth, tongue or throat which may be red and painful and/or cause difficulty in swallowing
- Chest pain
- Red patches on the skin

Very Common (more than 1 in 10 people)

- High levels of potassium in the blood, which can cause abnormal heart beats (palpitations).

Common (less than 1 in 10 people)

- An infection called thrush or candidiasis which can affect the mouth or vagina. It is caused by a fungus
- Headache
- Feeling sick (nausea)
- Diarrhoea
- Skin rashes.

Uncommon (less than 1 in 100)

- Being sick (vomiting).

Very Rare (less than 1 in 10,000 people)

- Fever (high temperature) or frequent infections
- Sudden wheeziness or difficulty breathing
- Mouth ulcers, cold sores and ulcers or soreness of the tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on the skin or inside the mouth, nose, vagina or bottom
- Inflammation of the eye which causes pain and redness
- The appearance of a rash or sunburn when your child has been outside (even on a cloudy day)
- Low levels of sodium in the blood
- Changes in blood tests
- Feeling weak, tired or listless, pale skin (anaemia)
- Heart problems
- Jaundice (the skin and the whites of the eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising
- Pains in the stomach, which can occur with blood in the faeces (poo)
- Pains in the chest, muscles or joints and muscle weakness
- Arthritis
- Problems with the urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in the urine.
- Kidney problems
- Sudden headache or stiffness of the neck, accompanied by fever (high temperature)
- Problems controlling movements
- Fits (convulsions or seizures)
- Feeling unsteady or giddy
- Ringing or other unusual sounds in the ears
- Tingling or numbness in the hands and feet
- Seeing strange or unusual sights (hallucinations)
- Depression
- Muscle pain and/or muscle weakness in HIV patients

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

5 How to store Septrin

- Keep out of the reach and sight of children.
- Keep away from direct heat or sunlight.
- Do not store above 25°C.
- Do not use the suspension after the expiry date shown on the bottle label and carton.
- Store in the original package with this leaflet.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6 Further information

What Septrin contains

Septrin is made up of two different medicines called sulfamethoxazole and trimethoprim. These medicines are sometimes given the combined name co-trimoxazole.

The other ingredients of Septrin 40 mg/200 mg per 5 ml Paediatric Suspension are: sorbitol solution (E420 ii), glycerol (E422), dispersible cellulose (E460), sodium carmellose, methyl hydroxybenzoate (E218), sodium benzoate (E211), saccharin sodium (E954), ethanol (alcohol), vanilla flavour, banana flavour, polysorbate 80 (E433) and purified water.

What Septrin looks like and contents of the pack

Septrin 40 mg/200 mg per 5 ml Paediatric Suspension is supplied to you in an amber-coloured glass bottle, containing 100 ml or 30 ml of an off-white liquid, which smells of banana and vanilla. The

medicine comes with a double-ended measuring spoon. One end of the spoon will give you 5 ml of the suspension and the other will give you 2.5 ml.

Each 5 ml of Septrin 40 mg/200 mg per 5 ml Paediatric Suspension contains 200 mg sulfamethoxazole and 40 mg trimethoprim.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:

UK

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0303123 9999 (UK Only)

Please be ready to give the following information:

Product name	Septrin 40 mg/200 mg per 5 ml Paediatric Suspension
Reference number	26946/0007

This is a service provided by the Royal National Institute of Blind People.

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Septrin is a registered trademark of Aspen

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