

PACKAGE LEAFLET

Package leaflet: Information for the patient

Septin Paediatric 40 mg/200 mg per 5ml Oral Suspension

Trimethoprim and Sulfamethoxazole

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for them.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Septin is and what it is used for.
2. What you need to know before your child takes Septin.
3. How to give Septin.
4. Possible side effects.
5. How to store Septin.
6. Contents of the pack and other information.

1. What Septin is and what it is used for

Septin Paediatric 40 mg/200 mg per 5 ml Oral Suspension (called 'Septin' in this leaflet) is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by bacteria. This medicine combination is also named as co-trimoxazole. Like all antibiotics, Septin only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Septin can be used to treat or prevent:

- lung infections (pneumonia) caused by the micro-organism, *Pneumocystis jirovecii* (previously known as *Pneumocystis carinii*) (some people call this 'PJP').

Septin can be used to treat:

- urinary bladder or urinary tract infections (water infections).
- respiratory tract infections such as bronchitis.
- ear infections such as otitis media.
- an infection called nocardiosis which can affect the lungs, skin and brain.
- an infection caused by a bacteria called toxoplasma (toxoplasmosis).
- an infection called brucellosis, if other treatments were not effective and in combination with other agents in line with national treatment guidelines.

Consideration should be given of official guidance on the appropriate use of antibacterial agents.

Septin Paediatric Suspension is indicated in children aged 12 years and under (infants (>6 weeks to <2 years old) and children (>2 to <12 years old).

2. What you need to know before your child takes Septin

Your child should not take Septin if:

- they are allergic to the active substance(s) sulfamethoxazole, trimethoprim, co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).

- 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 severe liver or severe kidney problems.
- they have ever had a problem with their blood causing bruises or bleeding (thrombocytopenia).
- you have been told that your child have a rare blood problem called porphyria, which can affect their skin or nervous system.
- Septrin should not be given to infants during the first 6 weeks of life

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

Warnings and precautions

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Septrin appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If your child has developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Septrin your child must not be re-started on Septrin at any time. If your child develops a rash or these skin symptoms, stop giving Septrin, seek urgent advice from a doctor and tell him that your child is taking this medicine.

Talk to your child's doctor or pharmacist before taking Septrin if:

- They have severe allergies or bronchial asthma.
- You have been told that your child is at risk for a rare blood disorder called porphyria.
- 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 a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- 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 or if your child takes medicines that can increase the amount of potassium in your child's blood, such as diuretics (water tablets, which help increase the amount of urine you produce) steroids (like prednisolone) and digoxin. High levels of potassium in your child's blood, can cause abnormal heart beats (palpitations), nausea, dizziness or headache.
- You have been told by your child's doctor that your child has an abnormally low level of sodium in their blood.
- You have been told by your child's doctor that your child has any serious disorders of the blood and blood forming tissues (haematological disorders). E.g. low blood cell counts.
- They have a kidney disease.

Other medicines and Septrin

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other 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.
- Cyclosporin, used after organ transplant surgeries.
- Blood thinners such as warfarin.
- Phenytoin, used to treat epilepsy (fits).

- Medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide.
- 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 such as spironolactone), steroids (like prednisolone) and digoxin.
- Azathioprine, may be used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting the immune system.
- Rifampicin, an antibiotic.
- Folinic acid.
- Contraceptive medicines.

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 drink plenty of fluid such as water while they are taking Septrin.

Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension

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

- 3.25 g sorbitol in every 5 ml spoonful. May have a mild laxative effect. Calorific value 2.6 kcal/g sorbitol. If you have been told by your child's doctor that they cannot tolerate or digest some sugars (have an intolerance to some sugars), contact your child's doctor before giving this medicinal product to your child.
- A small amount of ethanol (alcohol), less than 100 mg per 5 ml spoonful.
- Methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).
- Sodium 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'.
- The vanilla flavour contains sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to give Septrin 40 mg/200 mg per 5 ml paediatric suspension

Always ensure your child takes Septrin exactly as their doctor or pharmacist has told you. Check with their doctor or pharmacist if you are not sure.

Standard Dose

Standard dosage recommendations for acute infections

Children aged 12 years and under (infants (>6 weeks to <2 years old) and children (>2 to <12 years old) :

The schedules for children are according to the child's age and body weight provided in the table below:

STANDARD DOSAGE	
Age	Paediatric Suspension
6 to 12 years	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

	The dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day.
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- 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 you 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 jirovecii* (PJP).
- Treat infections caused by the bacteria toxoplasma (toxoplasmosis) or nocardia (nocardiosis) or brucella (brucellosis).

If your child has kidney problems their doctor may:

- Prescribe a lower dose of Septrin.
- Take blood to test whether the medicine is working properly.

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.
- Do not give your child a double dose 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 giving your child Septrin and tell your child's doctor immediately if your child has 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:

- 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.

Your child may also experience the following side effects with this medicine:

Very Common (more than 1 in 10 people)

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

Common (less than 1 in 10 people)

- A fungal infection called thrush or candidiasis which can affect the mouth or vagina.
- 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.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see Warnings and precautions).
- 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 (low blood cell counts).
- 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.
- Cough.
- Loss of appetite.
- Hypoglycaemia (an abnormally low level of glucose in the blood).
- Pseudomembranous colitis (Acute inflammation of the small and large intestinal mucosa with formation of pseudomembranous plaques over superficial ulceration.).
- Pancreatitis (Acute inflammation of the pancreas).
- Vertigo (An illusion of movement, either of the external world revolving around the individual or of the individual revolving in space).
- Hepatic necrosis (which may be fatal) (breakdown/death of liver tissue).

Unknown frequency (cannot be estimated from the available data)

- Psychotic disorder (a mental state in which you may lose touch with reality)

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland:

HPRA Pharmacovigilance.
Earlsfort Terrace
IRL - Dublin 2.
Tel: +353 1 6764971.
Fax: +353 1 6762517.
Website: www.hpra.ie.
e-mail: medsafety@hpra.ie.

Malta:

www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Septrin

- Keep this medicine out of the reach and sight of children.
- Store in the original package in order to protect from light.
- Store the bottle in the outer carton.
- Do not store above 25°C.
- Once opened, use within 6 weeks.
- Do not use the suspension after the expiry date shown on the bottle label and carton.
- 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. Contents of the pack and other information

What Septrin contains

- Septrin is made up of two different medicines called sulfamethoxazole and trimethoprim. Each 5 ml of Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension contains 200 mg sulfamethoxazole and 40 mg trimethoprim.
- The other ingredients of Septrin Paediatric 40 mg/200 mg per 5 ml suspension are: sorbitol solution (E420), glycerol (E422), dispersible cellulose (E460), carmellose sodium, methyl hydroxybenzoate (E218), sodium benzoate (E211), saccharin sodium (E954), ethanol (alcohol), vanilla flavour containing sulphur dioxide (E220), banana flavour, polysorbate 80 (E433) and purified water.

What Septrin looks like and contents of the pack

Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension is supplied to you in an amber-coloured glass bottle, containing 100 ml or 50 ml of an off-white banana and vanilla flavoured syrup. 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.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Aspen Pharma Trading Limited
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Citywest Business Campus,
Dublin 24,
Ireland

Manufacturer

Aspen Bad Oldesloe GmbH
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Medical Information Enquiries

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Ireland

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