PACKAGE LEAFLET

Package leaflet: Information for the patient

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

1. What Septrin Paediatric Suspension is and what it is used for

Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension (called 'Septrin Paediatric Suspension' 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, Septrin Paediatric Suspension only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Septrin Paediatric Suspension 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').

Septrin Paediatric Suspension 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 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.

Septrin 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 Septrin Paediatric Suspension

Your child should not take Septrin Paediatric Suspension **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 Paediatric Suspension should not be given to infants during the first 6 weeks of life
- you are pregnant (first 3 months) or might be pregnant

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

Warnings and precautions
Serious skin reactions, such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with Septrin Paediatric Suspension treatment. Stop using Septrin Paediatric Suspension and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Haemophagocytic lymphohistiocytosis
There have been very rare reports about excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations (haemophagocytic lymphohistiocytosis), which can be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay, contact your doctor immediately.

If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.

Talk to your child's doctor or pharmacist before taking Septrin Paediatric Suspension if:
- your child has ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking sulfamethoxazole or trimethoprim.
- 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 Paediatric Suspension
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 Paediatric Suspension can affect the way some medicines work. Also some other medicines can affect the way Septrin Paediatric Suspension works.
In particular tell your child's doctor of 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 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 Paediatric Suspension with food and drink
Your child should take Septrin Paediatric Suspension 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 Paediatric Suspension.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be taken during first three months of pregnancy. Treatment with trimethoprim in the first three months of pregnancy may increase the risk of miscarriage. Children born to mothers treated with trimethoprim during the first trimester of pregnancy may have an increased risk of birth defects, in particular neural tube defects (where the spine and spinal cord do not form properly), oral clefts (where the lip and palate do not form properly) and defects affecting the heart.

Septrin Paediatric Oral Suspension contains the following excipients with known effects:
- 2.3 g sorbitol in each 5 ml which is equivalent to 0.46 g/ml.
  Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- 10 mg of sodium benzoate (E 211) in each 10 ml dose which is equivalent to 0.75 mg of sodium benzoate per kg per body weight. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- 0.01 mg of ethanol in each 5 ml oral suspension which is equivalent to 0.002 mg/ml. The amount in 5ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine.The small amount of alcohol in this medicine will not have any noticeable effects.
- 5 mg of methyl p-hydroxybenzoate (E 218) per 5 ml, which may cause allergic reactions (possibly delayed).
- The vanilla flavour contains sulphur dioxide (E220) 0.00015 µL sulphur dioxide per 5 ml, which may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains 10.95 mg sodium (main component of cooking/table salt) in each 5ml dose. This is equivalent to 0.55% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to give Septrin paediatric suspension

Always ensure your child takes Septrin Paediatric Suspension 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.

- Septrin Paediatric Suspension should be taken for at least five days
- Make sure that your child finishes the course of Septrin Paediatric Suspension which their doctor has prescribed.

Special dose
The dose of Septrin Paediatric Suspension 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 Paediatric Suspension 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 Paediatric Suspension.
- Take blood to test whether the medicine is working properly.

If your child takes Septrin Paediatric Suspension 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 Paediatric Suspension.

If your child takes more Septrin Paediatric Suspension than they should
If your child takes more Septrin Paediatric Suspension 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 Paediatric Suspension they may:

- Feel or be sick.
- Feel dizzy or confused.

If you forget to give your child Septrin Paediatric Suspension

- 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 Paediatric Suspension 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 Paediatric Suspension and tell your child's doctor immediately if your child experiences any of the following symptoms:

- 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.
- Very rare: reddish patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu like symptoms (Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN)).
- Very rare cases of redness generalising to the whole body accompanied by fever (acute generalised exanthematous pustulosis (AGEP)) (see section 2).
- Unknown frequency: Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

Call the emergency department immediately if you experience multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug as it may be a sign of shock.

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.
- 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)
- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)

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
Website: www.hpra.ie

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

5. How to store Septrin Paediatric Suspension

- Keep this medicine out of the reach and sight of children.
- Keep the bottle in the outer carton in order to protect from light.
- Store the bottle in the outer carton.

- Do not store above 25ºC.
- 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 Paediatric Suspension contains

- Septrin Paediatric Suspension is made up of two different medicines called sulfamethoxazole and trimethoprim. Each 5 ml of Septrin Paediatric Suspension contains 200 mg sulfamethoxazole and 40 mg trimethoprim.
- The other ingredients of Septrin Paediatric suspension are:
  sorbitol (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 Paediatric Suspension looks like and contents of the pack

Septrin Paediatric 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

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