

## Package leaflet: Information for the patient

# Seprin® 40mg/200mg per 5ml paediatric suspension

(co-trimoxazole)

**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.

The name of your medicine is Seprin 40mg/200mg per 5ml paediatric suspension but will be referred to as Seprin throughout this leaflet.

### What is in this leaflet

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

## 1. What Seprin is and what it is used for

Seprin contains co-trimoxazole which is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is 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 PJP) caused by *Pneumocystis jirovecii*.
- Infections caused by *Toxoplasma* (toxoplasmosis).

Seprin 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.

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

Seprin 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 Seprin

### Your child should not take Seprin:

- If they are allergic to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).
- If they are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet).
- If they have severe liver or severe kidney problems.
- If they have ever had a problem with their blood causing bruises or bleeding (thrombocytopenia).
- If you have been told that your child has a rare blood problem called porphyria, which can affect their skin or nervous system.

- Seprin should not be given to infants during the first 6 weeks of life.
- If 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 Seprin.

### Warnings and precautions

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

- If they have severe allergies or asthma.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported with the use of Seprin appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Co-Trimoxazole.
- At the start of treatment, the occurrence of a generalised skin redness with pustules, accompanied by fever, should raise the suspicion of a serious reaction called generalised acute exanthematous pustulosis (AGEP) (see section 4).
- 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, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms with the use of Seprin your child must not be re-started on Seprin at any time.
- If your child develops a rash or these skin symptoms, stop giving Seprin, seek urgent advice from a doctor and tell him that your child is taking this medicine (see 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.
- If you have been told that your child is at risk for a rare blood disorder called porphyria.

- If 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.
- If they have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If they have a problem with their metabolism called phenylketonuria and are not on a special diet to help their condition.
- If they are underweight or malnourished.
- If you have been told by your child's doctor that your child has a lot of potassium in their blood. Concomitant administration of Seprin with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.
- If they have a kidney disease.
- If they have severe allergy or bronchial asthma.
- If your child has a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leucopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).

### Other medicines and Seprin

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This is because Seprin can affect the way some medicines work. Also some other medicines can affect the way Seprin 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 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 or ACE inhibitors (may be used to treat high blood pressure or some heart problems).
- 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.
- Folinic acid.
- Rifampicin, an antibiotic.
- Contraceptive medicines.

### Seprin with food and drink

Your child should take Seprin 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 Seprin.

### 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.

### Seprin contains

3.25g sorbitol in every 5ml spoonful. If you have been told by your child's doctor that they cannot tolerate or digest some sugars (has 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 100mg per 5ml spoonful.
- Methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).
- Benzoate, which may increase the risk of jaundice in newborn babies.
- Less than 1mmol sodium (23mg) per 5ml, i.e. essentially 'sodium free'.

## 3. How to give Seprin

Always ensure your child takes Seprin 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 dosage for children is equivalent to approximately 6mg trimethoprim and 30mg sulfamethoxazole per kg body weight per day.

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

Standard Dosage	
Age	Paediatric Suspension
6 to 12 years	two 5ml spoonfuls in a morning and two 5ml spoonfuls in an evening
6 months to 5 years	one 5ml spoonful in a morning and one 5ml spoonful in an evening
6 weeks to 5 months	one 2.5ml spoonful in a morning and one 2.5ml spoonful in an evening
Weight	Paediatric Suspension
>27kg	Two 5ml spoonfuls in the morning and two 5 ml spoonfuls in the evening
>20kg	One 5ml + one 2.5ml spoonful in the morning and one 5ml + one 2.5ml spoonful in the evening
>13kg	One 5ml spoonful in the morning and one 5ml spoonful in the evening
>7kg	One 2.5ml spoonful in the morning and one 2.5ml spoonful in the 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 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*.
- 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.  
Do not give your child a double dose to make up for a 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 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.
- 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)).
- 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.

#### 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)

- A fungal infection called thrush or candidiasis which can affect your child's 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.
- Very rare cases of redness generalising to the whole body (generalised acute exanthematous pustulosis (AGEP)) (see section 2).
- 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.
- Loss of appetite.

#### Unknown frequency (cannot be estimated from the available data)

- Psychotic disorder (a mental state in which you may lose touch with reality) (changes in behaviour)
- 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 the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Septrin

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package in order to protect from light.
- Keep away from direct heat.
- After first opening the bottle, use within 1 month.
- Do not use suspension after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
- If the suspension becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- 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 to protect the environment.

## 6. Contents of the pack and other information

#### What Septrin contains

The active ingredients in Septrin are trimethoprim and sulfamethoxazole.

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

Each 5ml suspension contains 40mg trimethoprim and 200mg sulfamethoxazole.

The other ingredients are sorbitol (70%), glycerol (E422), dispersible cellulose (E460), carmellose sodium, polysorbate 80, methyl parahydroxybenzoate (E218), sodium benzoate (E211), sodium saccharin (E954), banana flavour (propylene glycol E1520, sodium citrates E331), ethanol 96%, vanilla flavour (benzyl alcohol, caramel coloring E150d, propylene glycol E1520, glycerol E422, water) and purified water.

#### What Septrin looks like and contents of the pack

Septrin is off-white suspension, with characteristic smell of banana and vanilla.

It is available in amber-coloured glass bottle pack of 100ml.  
The medicine comes with a spoon which will measure 2.5ml and 5ml of the suspension.

**Manufactured by:** Alcala Farma, S.L, Avenida de Madrid 82, Alcala de Henares, 28802 Madrid, Spain.

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Septrin® 40mg/200mg per 5ml paediatric suspension; PL 18799/3055**

Leaflet date: 01.05.2026

**POM**

Septrin is a trademark of Aspen Global Incorporated.

**Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 0208 515 3763 to obtain the  
leaflet in a format suitable for you.**

## Package leaflet: Information for the patient

# Co-Trimoxazole 40mg/200mg per 5ml paediatric suspension

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.

The name of your medicine is Co-Trimoxazole 40mg/200mg per 5ml paediatric suspension but will be referred to as Co-trimoxazole throughout this leaflet.

### What is in this leaflet

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

## 1. What Co-trimoxazole is and what it is used for

Co-trimoxazole contains co-trimoxazole which is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by bacteria. Like all antibiotics, Co-trimoxazole only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Co-trimoxazole can be used to treat or prevent:

- Lung infections (pneumonia or PJP) caused by *Pneumocystis jirovecii*.
- Infections caused by *Toxoplasma* (toxoplasmosis).

Co-trimoxazole 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.

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

Co-trimoxazole 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 Co-trimoxazole

### Your child should not take Co-trimoxazole:

- If they are allergic to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).
- If they are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet).
- If they have severe liver or severe kidney problems.
- If they have ever had a problem with their blood causing bruises or bleeding (thrombocytopenia).
- If you have been told that your child has a rare blood problem called porphyria, which can affect their skin or nervous system.
  - Co-trimoxazole should not be given to infants during the first 6 weeks of life.
  - If 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 Co-trimoxazole.

### Warnings and precautions

Talk to your child's doctor or pharmacist before taking Co-trimoxazole:

- If they have severe allergies or asthma.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome (SIS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported with the use of Co-trimoxazole appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Co-Trimoxazole.
- At the start of treatment, the occurrence of a generalised skin redness with pustules, accompanied by fever, should raise the suspicion of a serious reaction called generalised acute exanthematous pustulosis (AGEP) (see section 4).
- 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, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms with the use of Co-trimoxazole your child must not be re-started on Co-trimoxazole at any time.
- If your child develops a rash or these skin symptoms, stop giving Co-trimoxazole, seek urgent advice from a doctor and tell him that your child is taking this medicine (see 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.

- If you have been told that your child is at risk for a rare blood disorder called porphyria.
- If 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.
- If they have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If they have a problem with their metabolism called phenylketonuria and are not on a special diet to help their condition.
- If they are underweight or malnourished.
- If you have been told by your child's doctor that your child has a lot of potassium in their blood. Concomitant administration of Co-trimoxazole with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.
- If they have a kidney disease.
- If they have severe allergy or bronchial asthma.
- If your child has a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leucopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).

### Other medicines and Co-trimoxazole

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This is because Co-trimoxazole can affect the way some medicines work. Also some other medicines can affect the way Co-trimoxazole 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 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 or ACE inhibitors (may be used to treat high blood pressure or some heart problems).
- 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.
- Folinic acid.
- Rifampicin, an antibiotic.
- Contraceptive medicines.

### Co-trimoxazole with food and drink

Your child should take Co-trimoxazole 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 Co-trimoxazole.

### 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.

### Co-trimoxazole contains

3.25g sorbitol in every 5ml spoonful. If you have been told by your child's doctor that they cannot tolerate or digest some sugars (has 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 100mg per 5ml spoonful.
- Methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).
- Benzoate, which may increase the risk of jaundice in newborn babies.
- Less than 1mmol sodium (23mg) per 5ml, i.e. essentially 'sodium free'.

## 3. How to give Co-trimoxazole

Always ensure your child takes Co-trimoxazole 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 dosage for children is equivalent to approximately 6mg trimethoprim and 30mg sulfamethoxazole per kg body weight per day.

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

Standard Dosage	
Age	Paediatric Suspension
6 to 12 years	two 5ml spoonfuls in a morning and two 5ml spoonfuls in an evening
6 months to 5 years	one 5ml spoonful in a morning and one 5ml spoonful in an evening
6 weeks to 5 months	one 2.5ml spoonful in a morning and one 2.5ml spoonful in an evening
Weight	Paediatric Suspension
>27kg	Two 5ml spoonfuls in the morning and two 5ml spoonfuls in the evening
>20kg	One 5ml + one 2.5ml spoonful in the morning and one 5ml + one 2.5ml spoonful in the evening
>13kg	One 5ml spoonful in the morning and one 5ml spoonful in the evening
>7kg	One 2.5ml spoonful in the morning and one 2.5ml spoonful in the evening

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

#### Special dose

The dose of Co-trimoxazole 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 Co-trimoxazole to:

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

#### If your child takes Co-trimoxazole 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 Co-trimoxazole.

#### If your child takes more Co-trimoxazole than they should

If your child takes more Co-trimoxazole 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 Co-trimoxazole they may

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

#### If you forget to give your child Co-trimoxazole

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 a forgotten dose.

## 4. Possible side effects

Like all medicines, Co-trimoxazole can cause side effects, although not everybody gets them.

Your child may experience the following side effects with this medicine.

Stop giving your child Co-Trimoxazole 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.
- 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)).
- 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.

#### 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)

- A fungal infection called thrush or candidiasis which can affect your child's 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.
- Very rare cases of redness generalising to the whole body (generalised acute exanthematous pustulosis (AGEP)) (see section 2).
- 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.
- Loss of appetite.

#### Unknown frequency (cannot be estimated from the available data)

- Psychotic disorder (a mental state in which you may lose touch with reality) (changes in behaviour)
- 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 the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Co-trimoxazole

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package in order to protect from light.
- Keep away from direct heat.
- After first opening the bottle, use within 1 month.
- Do not use suspension after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
- If the suspension becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- 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 to protect the environment.

## 6. Contents of the pack and other information

#### What Co-trimoxazole contains

The active ingredients in Co-trimoxazole are trimethoprim and sulfamethoxazole.

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

Each 5ml suspension contains 40mg trimethoprim and 200mg sulfamethoxazole.

The other ingredients are sorbitol (70%), glycerol (E422), dispersible cellulose (E460), carmellose sodium, polysorbate 80, methyl parahydroxybenzoate (E218), sodium benzoate (E211), sodium saccharin (E954), banana flavour (propylene glycol E1520, sodium citrates E331), ethanol 96%, vanilla flavour (benzyl alcohol, caramel coloring E150d, propylene glycol E1520, glycerol E422, water) and purified water.

#### What Co-trimoxazole looks like and contents of the pack

Co-trimoxazole is off-white suspension, with characteristic smell of banana and vanilla.

It is available in amber-coloured glass bottle pack of 100ml.

The medicine comes with a spoon which will measure 2.5ml and 5ml of the suspension.

**Manufactured by:** Alcala Farma, S.L, Avenida de Madrid 82, Alcala de Henares, 28802 Madrid, Spain.

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Co-Trimoxazole 40mg/200mg per 5ml paediatric suspension;  
PL 18799/3055**

**POM**

Leaflet date: 01.05.2026

**Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 0208 515 3763 to obtain the  
leaflet in a format suitable for you.**