

Package Leaflet: Information for the User

Septin® 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 this medicine is Septin® 40mg/200mg per 5ml Paediatric Suspension but it will be referred to as Septin throughout the remainder of this leaflet.
- Septin is also available in another strength.

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 40mg/200mg per 5ml Paediatric Suspension 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 or PJP) caused by a bacteria called *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*).
- Infections caused by a bacteria called *Toxoplasma* (toxoplasmosis).

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.

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

Your child should not take Septin:

- If they are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of Septin (see section 6: Contents of the pack and other information).
- 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 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 have a rare blood problem called porphyria, which can affect their skin or nervous system.

Septin should not be given to your child if they are less than 6 weeks old or were premature. Unless it is for the treatment or prevention of PJP. In this case, Septin should not be given if they are less than 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 Septin.

Warnings and precautions

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

- If they have severe allergies or asthma.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Septin 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 Septin your child must not be re-started on Septin at any time.
- If your child develops a rash or these skin symptoms, stop giving Septin, seek urgent advice from a doctor and tell him that your child is taking this medicine.
- 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.
- 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 Septin

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This is because Septin can affect the way some medicines work. Also some other medicines can affect the way Septin 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), steroids (like prednisolone) and digoxin.
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting the immune system.
- Folinic acid.
- Rifampicin, an antibiotic.
- Contraceptive medicines.

Septin with food and drink

Your child should take Septin 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 Septin.

Septin 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.
- Methylparahydroxybenzoate, 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 Septin

Always ensure your child takes Septin exactly as their doctor or pharmacist has told you. 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 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.
- Septin should be taken for at least five days
- Make sure that your child finishes the course of Septin which their doctor has prescribed.

Special dose

The dose of Septin 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 Septin 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 Septin 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 Septin.

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 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

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 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 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.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see Warnings and precautions).
- 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.

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.

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 packaging to protect from light.
- Do not use Septrin after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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

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

Also contains sorbitol 70%, glycerol (E422), dispersible cellulose, sodium carmellose, polysorbate 80, methylparahydroxybenzoate (E218), sodium benzoate (E211), saccharin sodium, banana flavour (propylene glycol E1520, sodium citrate E331), ethanol (96%), vanilla flavour (benzyl alcohol, caramel colouring E150d, propylene glycol E1520, glycerol E422, water) and purified water.

What Septrin looks like and contents of the pack

Septrin is an off-white suspension with characteristic banana and vanilla odour. The suspension is supplied in a brown glass bottle with metal screw cap. The medicine comes with a plastic double-ended 5ml/2.5ml measuring spoon.

Septrin is available in packs of 1 bottle containing 100ml of suspension.

Manufactured by

Alcalá Farma, S.L, Avenida de Madrid 82, Alcalá de Henares, 28802 Madrid, Spain.

Procured from within the EU by the Product Licence Holder:

MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Leaflet dated 23rd February 2017

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To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.

Package Leaflet: Information for the User

Co-trimoxazole 40mg/200mg per 5ml Paediatric Suspension (co-trimoxazole)

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- 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 this medicine is Co-trimoxazole 40mg/200mg per 5ml Paediatric Suspension but it will be referred to as Co-trimoxazole throughout the remainder of this leaflet.
- Co-trimoxazole is also available in another strength.

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 40mg/200mg per 5ml Paediatric Suspension 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, 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 a bacteria called *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*).
- Infections caused by a bacteria called 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.

2. What you need to know before your child takes Co-trimoxazole

Your child should not take Co-trimoxazole:

- If they are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of Co-trimoxazole (see section 6: Contents of the pack and other information).
- 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 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 have a rare blood problem called porphyria, which can affect their skin or nervous system.

Co-trimoxazole should not be given to your child if they are less than 6 weeks old or were premature. Unless it is for the treatment or prevention of PJP. In this case, Co-trimoxazole should not be given if they are less than 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 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, toxic epidermal necrolysis) 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.
- 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 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.
- 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.
- 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), steroids (like prednisolone) and digoxin.
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting the immune system.
- Folic 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 drink plenty of fluid such as water while they are taking Co-trimoxazole.

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.
 - Methylparahydroxybenzoate, 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.

Usual dose

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

- 6 to 12 years old: 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.
- 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 jiroveci*.
- 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 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

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 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 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.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see Warnings and precautions).
- 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.

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.

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 packaging to protect from light.
- Do not use Co-trimoxazole after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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**

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

Also contains sorbitol 70%, glycerol (E422), dispersible cellulose, sodium carmellose, polysorbate 80, methylparahydroxybenzoate (E218), sodium benzoate (E211), saccharin sodium, banana flavour (propylene glycol E1520, sodium citrate E331), ethanol (96%), vanilla flavour (benzyl alcohol, caramel colouring E150d, propylene glycol E1520, glycerol E422, water) and purified water.

What Co-trimoxazole looks like and contents of the pack

Co-trimoxazole is an off-white suspension with characteristic banana and vanilla odour. The suspension is supplied in a brown glass bottle with metal screw cap. The medicine comes with a plastic double-ended 5ml/2.5ml measuring spoon.

Co-trimoxazole is available in packs of 1 bottle containing 100ml of suspension.

Manufactured by

Alcalá Farma, S.L, Avenida de Madrid 82, Alcalá de Henares, 28802 Madrid, Spain.

Procured from within the EU by the Product Licence Holder:

MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Leaflet dated 23rd February 2017

Leaflet coded xxxxxxxxxxxx

To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.