PATIENT INFORMATION LEAFLET

SULPHATRIM ORAL SUSPENSION BP (40 MG + 200 MG) PER ML

(Trimethoprim BP 40 mg and Sulphamethoxazole BP 200 mg)

[Trimethoprim BP, Sulphamethoxazole BP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT PAEDIATRIC CO-TRIMOXAZOLE ORAL SUSPENSION BP 240 MG/ML IS AND WHAT IT IS USED FOR

It contains the active substance trimethoprim and sulphamethoxazole. It is a combination of two different antibiotics called co-trimoxazole, which is used to treat infections caused by bacteria. Like all antibiotics. It is indicated in children aged 12 years and under (infants (>6 weeks to <2 years old) and children (>2 to <12 years old) for the treatment of the following infections when owing to sensitive organisms. Treatment and prevention of pneumocystis jirovecii pneumonitis (PJP).Treatment and prophylaxis of toxoplasmosis, nocardiosis. It can affect the lungs, skin and brain. The following infections may be treated with co-trimoxazole where there is bacterial evidence of sensitivity to co-trimoxazole and good reason to prefer the combination of antibiotics in co-trimoxazole to a single antibiotic. Acute uncomplicated urinary tract infection. Acute otitis media. Acute exacerbation of chronic bronchitis.

2. BEFORE YOU USE PAEDIATRIC CO-TRIMOXAZOLE ORAL SUSPENSION BP 240 MG/ML

Do not use this medicinal product. If you are known hypersensitivity to sulphonamides, trimethoprim and sulphamethoxazole or any other component of the product. Severe hepatic parenchymal damage. Patients with severe renal insufficiency where repeated measurements of the plasma concentration cannot be performed. It should not be given to patients with a history of drug-induced immune thrombocytopenia with use of trimethoprim and/or sulphonamides. It should not be given to patients with acute porphyria. It should not be given to infants during the first 6 weeks of life.

Warnings and precautions:

Fatalities, although very rare, have occurred due to severe reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, other blood dyscrasias and hypersensitivity of the respiratory tract. Cutaneous reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis with the use of this medicinal product. Use with caution in asthma blood disorders, decreased kidney function, decreased liver function, elderly people, infants under 6 weeks of age, lack of the enzyme G6PD in the blood. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions)

are present, consult to the physician. It should be given with caution to patients with severe atopy or bronchial asthma. It should not be used in the treatment of streptococcal pharyngitis due to group a beta-haemolytic streptococci, eradication of these organisms from the oropharynx is less effective than with penicillin. The administration of this medicinal product to patients known or suspected to be at risk of porphyria should be avoided. Both trimethoprim and sulphonamides have been associated with clinical exacerbation of porphyria. Close monitoring of serum potassium and sodium is warranted in patients at risk of hyperkalaemia and hyponatraemia. Co-Trimoxazole has been associated with metabolic acidosis. Close monitoring is always advisable when metabolic acidosis is suspected. Except under careful supervision. It should not be given to patients with serious haematological disorders. It has been given to patients receiving cytotoxic therapy with little or no additional effect on the bone marrow or peripheral blood. The administration of this medicinal product should be avoided in infants younger than eight weeks in view of the predisposition of young infants to hyperbilirubinaemia. The combination of antibiotics in co-trimoxazole should only be used where, in the judgment of the physician, the benefits of treatment outweigh any possible risks, and patients with rare hereditary problems of fructose intolerance should not take this medicine.

Using other medicines: Please tell your physician, health care provider or pharmacist if you are taking or have recently taken any other medicines. Tell your physician if you are taking any of the following medicines: Zidovudine: It may increase the risk of hematological adverse reactions to co-trimoxazole. Cyclosporin: reversible deterioration in renal function for treated with co-trimoxazole and cyclosporin following renal transplantation, Rifampicin: results in a shortening of the plasma half-life of trimethoprim after a period of about one week. Diuretics (thiazides): there appears to be an increased risk of thrombocytopenia with or without purpura, Pyrimethamine: patients receiving pyrimethamine at doses in excess of 25 mg weekly may develop megaloblastic anemia should co-trimoxazole be prescribed concurrently. Warfarin: anticoagulant activity of warfarin via stereo-selective inhibition of its metabolism. Phenytoin: co-trimoxazole prolongs the half-life of phenytoin and if co-administered could result in excessive phenytoin effect. Digoxin: increase plasma digoxin levels in a proportion of older patients. Methotrexate: co-trimoxazole may increase the free plasma levels of methotrexate. Lamivudine: administration of trimethoprim/sulfamethoxazole 160 mg/800 mg causes a 40% increase in lamivudine exposure because of the trimethoprim component. Lamivudine has no effect on the pharmacokinetics of trimethoprim or sulfamethoxazole. Sulphonylurea and hypoglycemic agents: Interaction is uncommon but potentiation has noted. Hyperkalaemia: caution should be exercised in patients taking any other drugs that can cause hyperkalaemia, ACE inhibitors angiotensin receptor blockers and potassium-sparing diuretics such as spironolactone. Repaglinide: which may result in hypoglycemia. Folinic acid: folinic acid supplementation has been shown to interfere with the antimicrobial efficacy of trimethoprimsulfamethoxazole. There are observe in Pneumocystis jirovecii pneumonia prophylaxis and treatment. Contraceptives, Azathioprine. If you have any further questions about this you should speak to your physician.

Taking paediatric co-trimoxazole oral suspension BP 240 mg/mL with food and drink: Your child should take this medicinal product with some food or drink. This will stop those 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 this medicinal product.

Pregnancy and Lactation: Take advice by talk to physician or pharmacist before taking. **Pregnancy:** Co-Trimoxazole should not be used in pregnancy, particularly in the first trimester, unless clearly necessary. Folate supplementation should be considered if Co-Trimoxazole is used in pregnancy. **Breast-feeding:** The components of co-trimoxazole (trimethoprim and sulfamethoxazole) are excreted in breast milk. Administration of co-trimoxazole should be avoided in late pregnancy and in lactating mothers where the mother or infant has, or is at particular risk of developing, hyperbilirubinaemia.

Driving and using machines: Effects on ability to drive and use machines on driving performance or the ability to operate machinery co-trimoxazole should be borne in mind when considering the patients ability to operate machinery.

3. HOW TO USE PAEDIATRIC CO-TRIMOXAZOLE ORAL SUSPENSION BP 240 MG/ML

Always use paediatric co-trimoxazole oral suspension BP 240 mg/mL exactly or as directed by physician or health care provider has told you. **Method of administration:** Oral, Treatment should be continued until the patient has been symptom free for two days; the majority will require treatment for at least 5 days. If clinical improvement is not evident after 7 days therapy, the patient should be reassessed. Use the suspension within 28 days after opening the container.

Posology:

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 standard dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day, given in two equally divided doses. The schedules for children are according to the child's age and provided as per below:

6 to 12 years: 10 ml every 12 hours, seven days per week. **6 months to 5 years:** 5 ml every 12 hours, seven days per week. **6 weeks to 5 months:** 2.5 ml every 12 hours, seven days per week. The daily dose given on a treatment day approximates to 150 mg trimethoprim/m2/day and 750 mg^2 sulfamethoxazole/m^2/day. The total daily dose should not exceed 320 mg trimethoprim and 1600 mg sulfamethoxazole. Treatment should be continued until the patient has been symptom free for two days; the majority will require treatment for at least 5 days. If clinical improvement is not evident after 7 days therapy, the patient should be reassessed. It may be preferable to take Co-Trimoxazole with some food or drink to minimize the possibility of gastrointestinal disturbance.

If you more paediatric co-trimoxazole oral suspension BP 240 mg/mL than you should: Do not use more than the recommended dose. If taking more than the recommended dose may cause symptoms are likely nausea, vomiting, dizziness and confusion, bone marrow depression of over dosage. Treatment if vomiting has not occurred, induction of vomiting may be desirable. Gastric lavage may be useful, though absorption from the gastrointestinal tract is normally very rapid and complete within approximately two hours. This may not be the case in gross over dosage dependent on the status of renal function administration of fluids is recommended if urine output is low. Both trimethoprim and active sulfamethoxazole are moderately dialyzable by haemodialysis. Peritoneal dialysis is not effective.

If you forget to paediatric co-trimoxazole oral suspension BP 240 mg/mL: If you forget to take a dose, do not take a two doses at the same time to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your physician or pharmacist. **Important information about some of the ingredients of** this medicinal product excipients with known effects: It contains Sodium methyl hydroxybenzoate, which may cause allergic reactions. It is also contain aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

4. POSSIBLE SIDE EFFECTS

Like all medicines can cause side effects, although not everybody gets them. 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**: skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported. **Unknown frequency:** An allergic type reaction in which you may develop flu-like symptoms with fever, rash, swollen glands, and abnormal blood test results. These may be symptoms of a condition

known as DRESS and can be severe and life-threatening. **Very Common;** High levels of potassium in your blood, which can cause abnormal heart beats (palpitations). **Common;** a fungal infection called thrush or candidiasis which can affect the mouth or vagina, headache, feeling sick (nausea), diarrhoea, skin rashes. **Uncommon:** Being sick (vomiting). **Very Rare;** 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. Very rare cases of redness generalising to the whole body (acute generalised exanthematous pustulosis (AGEP). 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. Problems controlling movements. Fits, feeling unsteady or giddy. Ringing or other unusual sounds in the ears. Tingling or numbness in the hands and feet. Hallucinations, depression, muscle pain and/or muscle weakness in HIV patients, cough, loss of appetite, hypoglycaemia, pseudomembranous colitis, vertigo, hepatic necrosis. **Unknown frequency:** Psychotic disorder, plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever. If any of above the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

5. HOW TO STORE PAEDIATRIC CO-TRIMOXAZOLE ORAL SUSPENSION BP 240 MG/ML

Keep this medicine out of the sight and reach of children. Do not store above 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as Trimethoprim BP 40 mg and Sulphamethoxazole BP 200 mg/mL. Each ml contains: Trimethoprim BP 40 mg and Sulphamethoxazole BP 200 mg/mL **Excipients:** Sodium methyl hydroxybenzoate, Sodium Propyl hydroxybenzoate, Citric acid monohydrate, Sucrose, Carmellose sodium HVP (Carboxy methyl cellulose sodium), Sodium citrate, Aspartame, Disodium Edetate, Essence mixed fruit, Colour Erythrosine (Supra), Polysorbate-80 (Tween-80), Colloidal anhydrous silica (Aerosil), Purified water. **Shelf life:** 36 Months**. Size:** White to off white coloured suspension. Such one 100 ml amber PET bottle is packed in printed carton along with a packaging insert.

Manufactured by:

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal.:- Kalol,
Dist.:- Gandhinagar, Gujarat State, India.
Phone: +91-079-41078096
Telefax: +91-79-41078062

Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Lincoln Pharmaceuticals Limited Trimul Estate, Khatraj, Tal.:- Kalol, Dist.:- Gandhinagar, Gujarat State, India. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: hiren@lincolnpharma.com Website: www.lincolnpharma.com	**Abacus Pharma (A) Ltd** Kigali city market, B1-R85, PO Box 4344, Kigali, Rwanda. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: abacuspharmacist@gmail.com

Date of publication or revision

07.12.2023