PATIENT INFORMATION LEAFLET
CO-TRIMOXAZOLE TABLETS BP 960 MG [SULPHATRIM-960]
(Sulphamethoxazole BP 800 mg and Trimethoprim BP 160 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 CO-TRIMOXAZOLE TABLETS BP 960 MG 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 for the treatment of the following infections. Nocardiosis, acute uncomplicated urinary tract infection (UTI), acute otitis media and acute exacerbation of chronic bronchitis. Treatment and prevention of Pneumocystis jirovecii pneumonitis and toxoplasmosis.

2. BEFORE YOU USE CO-TRIMOXAZOLE TABLETS BP 960 MG

Do not use this medicinal product. If you are known hypersensitivity to sulphonamides, trimethoprim and sulphamethoxazole or any other component of the product. Marked liver parenchymal damage, severe renal insufficiency, premature babies nor to full-term infants during the first 6 weeks of life.

Warnings and precautions:

Rare fatalities due to severe reactions including fulminant hepatic necrosis, agranulocytosis, aplastic anaemia, other blood dyscrasias and hypersensitivity of respiratory tract. Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. Elderly patients group with impaired kidney and/or liver function and/or concomitant use of other drugs, patients at risk of acute porphyria or serious haematological disorders or receiving cytotoxic therapy or at risk of hyperkalaemia. Raresulphonamidc crystals observedin treated patients, particularly in malnourished patients. Possible asymptomatic changes in haematological laboratory indices due to lack of available folate in folate deficient patients or to the elderly. Haemolysis in G-6-PD deficient patients. Should be given with caution to patients with severe allergy or bronchial asthma or in phenylketonuric patient sand in the treatment of streptococcal pharyngitis. **Pregnancy and Lactation:** Not recommended in pregnant and breast-feeding women. **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: Trimethoprim interfere in serum/plasma creatinine estimation when alkaline picrate is used. Co-trimoxazole with zidovudine increase risk of haematological adverse reactions. Reversible deterioration in renal function in patients treated with co-trimoxazole and cyclosporin following renal transplantation. Shortening of plasma half-

life of trimethoprim with rifampicin after period of about one week. Simultaneous administered of trimethoprim with drugs such as digoxin, procainamide, amantadine may increase in plasma concentration of one or both drugs. In elderly patients concurrently receiving diuretics, increased risk of thrombocytopenia with or without purpura. Occasional reports suggest that patients receiving pyrimethamine at doses in excess of 25 mg weekly may develop megaloblastic anaemia should co- trimoxazole be prescribed concurrently. Co-trimoxazole potentiates anticoagulant activity of warfarin via inhibition of its metabolism. Co-trimoxazole with phenytoin results in excessive phenytoin effect. Close monitoring of patient's condition and serum phenytoin levels arc advisable. Co-trimoxazole increases free plasma levels of methotrexate and 40% increase in lamivudine. Interaction with sulphonylurea hypoglycaemic agents and drugs that can cause hyperkalemia. If you have any further questions about this you should speak to your physician.

Taking co-trimoxazole tablets BP 960 mg 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:** Not recommended in pregnant and breast-feeding women. **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 CO-TRIMOXAZOLE TABLETS BP 960 MG

Always use co-trimoxazole tablets BP 960 mg exactly or as directed by physician or health care provider has told you. **Method of administration:** Oral, Oral with some food or water.

Posology:

Strength of Tablet	80 mg/400 mg	160 mg/800 mg
Standard Dose for Acute Infection & Prevention (See below)	2 tablets every 12 hours	1 tablet every 12 hours

Standard dosage recommendations for acute infections.

Adults and children over 12 years: 160 mg trimethoprim/800 mg sulfamethoxazole every 12 hourly. Continued treatment until patient has been symptom free for 2 days; majority require treatment for at least 5 days. If no improvement, reassess after 7 days therapy. 1 to 3 days short-term therapy was effective for acute uncomplicated lower UTI. **The elderly:** Refer Special Warnings and Precautions for use. **Impaired hepatic function:** No data for dosage in patients with impaired hepatic function.

Impaired renal function:

Creatinine Clearance (ml/min)	Recommended Dose
> 30	Standard Dose
15 to 30	Half the Standard Dosage
< 15	Not recommended

Pneumocystis jirovecii (P. carinii) pneumonitis and Toxoplasmosis: Treatment: 20 mg trimethoprim and 100 mg sulfamethoxazole per kg of body weight per day in two or more divided doses for two weeks to obtain peak plasma or serum levels of trimethoprim of greater than or equal to 5 mg/ml.

Prevention: Adults: The following dose schedules may be used: 160 mg trimethoprim/800 mg sulfamethoxazole 7 days/week or 3 times/week on alternate days. 320 mg trimethoprim/1600 mg sulfamethoxazole per day in 2 divided doses 3 times/week on alternate days.

Children: The following dose schedules may be used for the duration of the period at risk: Standard dosage taken in two divided doses, 7 days/week or 3 times per week on alternate days. Standard dosage taken in 2 divided doses or single dose, 3 times per week on consecutive days.

Daily dose on treatment day approximates to 150 mg trimethoprim/m2/day and 750 mg sulfamethoxazole/m2/day. Not exceeding 320 mg trimethoprim and 1600 mg sulfamethoxazole.

Nocardiosis: Adult doses of 6 to 8 tablets daily for up to 3 months have been used. (One tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim).

If you more co-trimoxazole TABLETSBP 960 mg 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 induction of vomiting, gastric lavage and moderately dialysable by haemodialysis may be useful as rapid and complete absorption within approximately 2 hours from the GIT. Peritoneal dialysis is not effective.

If you forget to co-trimoxazole Tablets BP 960 mg: 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines can cause side effects, although not everybody gets them. Very common: Hyperkalacmia Common: Monilial overgrowth, Headache, Nausea, diarrhea, Skin rashes Uncommon: Vomiting. Very rare: Leucopenia, neutropenia, thrombocytopenia, agranulocytosis, megaloblastic anaemia, aplastic anaemia, haemolytic anaemia, methaemoglobinaemia, eosinophilia, purpura, haemolysis in G-6-PD deficient patients, Serum sickness, anaphylaxis, allergic myocarditis, angioedema, drug fever, allergic vasculitis resembling Henoch-Schoenleinpurpura, periarteritisnodosa, systemic lupus erythematosus, Hypoglycaemia, hyponatraemia, anorexia, depression, hallucinations, cough, shortness of breath, pulmonary infiltrates, glossitis, stomatitis, pseudomembranous colitis, pancreatitis, uveitis, Elevation of serum transaminases, elevation of bilirubin levels, cholestatic jaundice, hepatic necrosis, photosensitivity, exfoliative dermatitis, fixed drug eruption, erythema multiforme, SCARs: SJS and TEN, Arthralgia, myalgia, Impaired renal function, interstitial nephritis, Severe hypersensitivity reactions, rash, fever, neutropenia, thrombocytopenia, raised liver enzymes, hyperkalacmia, hyponatraemia. 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 CO-TRIMOXAZOLE TABLETS BP 960 MG

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 160 mg and Sulphamethoxazole BP 800 mg. Each uncoated tablets contains: Trimethoprim BP 160 mg and Sulphamethoxazole BP 800. **Excipients:** Maize Starch BP, Sodium Lauryl Sulfate BP, Sodium Methyl Hydroxy benzoate BP, Sodium Propyl Hydroxy benzoate BP, Purified Water BP, Purified Talc BP, Sodium Starch Glycolate (Type-A) BP, Povidone (PVPK- 30) BP, Magnesium Stearate BP. **Shelf life:** 36 Months**. Size:** White to off-white coloured, round shaped, flat, uncoated tablets, breakline on one side and plain on other side. Such 10 Tablets are packed in Alu-PVC Blister Pack. Such 10 Alu-PVC Blisters are packed in a printed Carton with Packing 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

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