Patient information leaflet

1. Name of the Product?
Co-trimoxazole tablets BP 480 mg

2. Description of the Product
White colored, circular shaped beveled edge uncoated tablet having break line on one side and other side plain

3. What is in the medicine?

Co-trimoxazole tablets BP 480 mg contains Sulfamethoxazole BP and Trimethoprim BP

4. Strength of the medicine ?

Each uncoated tablet contains

Sulfamethoxazole BP 400 mg

Trimethoprim BP 80. mg

Excipients q.s.

5. What is this medicine used for?
Co-trimoxazole should only be used where, in the judgement of the physician, the benefits of treatment outweigh any possible risks; consideration should be given to the use of a single effective antibacterial agent.

Co-trimoxazole is an antibacterial agent. Co-trimoxazole is effective in vitro against a wide range of gram-positive and gram-negative organisms. It is not active against Mycobacterium tuberculosis, mycoplasma or Treponema pallidum, Pseudomonas aeruginosa is usually insensitive.

Co-trimoxazole is indicated for the treatment of adults, adolescents and children from 12-18 years of age.

Co-trimoxazole is indicated for the treatment of the following infections when owing to sensitive organisms

- Treatment and prophylaxis (primary and secondary) of Pneumocytosis jiroveci pneumonitis or PJP.

- Treatment and prophylaxis of toxoplasmosis

- Treatment of nocardoasis.

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.

- Treatment of acute uncomplicated urinary tract infections
- Treatment of acute exacerbation of chronic bronchitis
- Treatment of acute otitis media

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

6. How much and how often should you use this medicine?

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Posology

General dosage recommendations

Where dosage is expressed as "tablets" this refers to the adult tablet, i.e 80 mg Trimethoprim BP and 400 mg Sulfamethoxazole BP. If other formulations are to be used appropriate adjustment should be made.

Standard dosage recommendations for acute infections

Adults (>18 years old):

STANDARD DOSAGE	
Age	**Forte tablets**
>18 years old	2 tablets every 12 hours

Children over 12 years old (>12 to <18 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 in the table below:

Age	**Forte tablets**
>12 to <18 years old	2 tablets every 12 hours

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 of therapy, the patient should be reassessed.

As an alternative to Standard Dosage for acute uncomplicated lower urinary tract infections, short- term therapy of 1 to 3 days' duration has been shown to be effective

Method of administration:

Oral.

It may be preferable to take Co-Trimoxazole with some food or drink to minimise the possibility of gastrointestinal disturbances.

Special Dose

The dose of Co-Trimoxazole and how long you need to take it depends on the infection you have and how bad it is. Your doctor may prescribe you a different dose or length of course of Co-Trimoxazole to:

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

If you have kidney problems your doctor may:

- Prescribe a lower dose of Co-Trimoxazole.
- Take blood to test whether the medicine is working properly. If you take Co-Trimoxazole for a long time your doctor may:
- Take blood to test whether the medicine is working properly.
- Prescribe folic acid (a vitamin) for you to take at the same time as Co-Trimoxazole.

7. When should you not take this medicine?

Co-trimoxazole tablets BP 480 mg is contraindicated in:

Hypersensitivity to the active substances sulphonamides, trimethoprim, co-trimoxazole or to any of the excipients

Contra-indicated in patients with severe hepatic parenchymal damage. Contra-indicated in patients with severe renal insufficiency where repeated measurements of the plasma concentration cannot be performed.

Co-trimoxazole should not be given to infants during the first 6 weeks of life.

Co-trimoxazole should not be given to patients with a history of drug-induced immune thrombocytopenia with use of trimethoprim and/or sulphonamides.

Co-trimoxazole should not be given to patients with acute porphyria.

8. Undesirable Effects

Like all medicines Co-Trimoxazole can cause side effects, although not everybody gets them. You may experience the following side effects with this medicine.

Stop taking Co-Trimoxazole and tell your doctor immediately if you have 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 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)
- 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 your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom

- Inflammation of the eye which causes pain and redness
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Low levels of sodium in your blood
- Changes in blood tests
- Feeling weak, tired or listless, pale skin (anaemia)
- Heart problem
- Jaundice (the skin and the whites of your eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising
- Pains in your stomach, which can occur with blood in your faeces (stools)
- Pains in your chest, muscles or joints and muscle weakness
- Arthritis
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual.
- Blood or cloudiness in your urine
- Kidney problems
- Sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- Problems controlling your movements
- Fits (convulsions or seizures)
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Tingling or numbness in your hands and feet
- Seeing strange or unusual sights (hallucinations)
- Depression
- Muscle pain and/or muscle weakness in HIV patients
- Loss of appetite

9. What other medicine or food should be avoided whilst taking this medicine

As directed by the physician.

10. What should you do if you miss a dose?

Ask your doctor for advice.

11. How should you keep this medicine?

Keep this medicine out of the reach and sight of children.
Do not store above 30°C.
Keep the blister in the outer carton in order to protect from light.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment

12. Signs and Symptoms of Overdosage

If you have taken too much Co-Trimoxazole you may:

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

13. What to do when you have taken more than the recommended dosage

If you have accidentally taken too many tablets, talk to your doctor straight away, or go to your nearest emergency unit. You may require medical attention. Remember to take your medicine with you, and show it to your doctor or the staff of the emergency unit. If you have run out of tablets, take the empty packaging along with you.

14. Name/Logo of Manufacturer/Importer/Marketing Authorisation Holder

Sun Enterprises LTD.

Rwanda

Mobile +250788308788

Email sanjay@sunenp.net

15. Care that should be taken while taking this medicine

Talk to your doctor or pharmacist before taking Co-Trimoxazole:

- If you have severe allergies or asthma.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms) 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.
- 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 you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms with the use of Co-Trimoxazole you must not be re-started on Co-Trimoxazole at any time.
- If you develop a rash or these skin symptoms, stop taking Co-Trimoxazole, seek urgent advice from a doctor and tell him that you are taking this medicine.
- 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 you are at risk for a rare blood disorder called porphyria.
- If you have a kidney disease.
- If you don't have enough folic acid (a vitamin) in your body - which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia.
- If you have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells. If you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition.

- If you are elderly.
- If you are underweight or malnourished.
- If you have been told by your doctor that you have a lot of potassium in your 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 you have 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).

16. Date of Revision of PIL
