

## PAEDIATRIC CO-TRIMOXAZOLE TABLETS B.P.

### COMPOSITION :

Each uncoated tablet contains :  
Trimethoprim B.P. 20 mg  
Sulphamethoxazole B.P. 100 mg  
Excipients Q.S.

### THERAPEUTIC CLASS :

Antibacterial

### PHARMACOLOGICAL ACTIONS :

Co-trimoxazole tablets is a combination of trimethoprim and sulphamethoxazole and results in synergistic effects causing a bactericidal action (in vitro). The action of co-trimoxazole is achieved by the sequential blocking of two enzymes essential in folic acid synthesis in the organism.

#### *Pharmacokinetics :*

*Absorption :* Trimethoprim/sulphamethoxazole is rapidly absorbed following PO administration. T max is 1 to 4h. Steady state is achieved after 3 days.

*Distribution :* 70% of sulphamethoxazole and 44% of trimethoprim is protein bound. Trimethoprim/sulphamethoxazole is distributed to sputum, vaginal fluid, and middle ear fluid. Trimethoprim/sulphamethoxazole passes the placental barrier and is excreted in human milk.

*Metabolism :* Metabolism of sulphamethoxazole is primarily by N 4 -acetylation. The principal metabolites of trimethoprim are the 1- and 3-oxides and the 3- and 4-hydroxy derivatives. The free forms are considered therapeutically active. *Elimination :* Serum t<sub>1/2</sub> of sulphamethoxazole and trimethoprim is 10h and 8 to 10 h, respectively. Trimethoprim/sulphamethoxazole is primarily eliminated by kidneys through glomerular filtration and tubular secretion. Urine concentrations are higher than blood concentrations.

### INDICATIONS :

Chronic bronchitis, Ear infections, Infection of the bladder or tubes that pass urine (urinary tract infection), Prevention of pneumonia caused by the bacterium pneumocystis carinii (PCP). The risk of this infection is increased in patients with decreased immune system function.

### CONTRAINDICATIONS :

Hypersensitivity, It should not be used in patients suffering from liver parenchymal damage, or a severe renal insufficiency, during pregnancy, lactation & patients with megaloblastic anaemia or blood dyscrasias. Use of the substance in premature or new-born infants during the first two months of life is contra-indicated. Should not be given in the presence of vitamin B<sub>12</sub> and folic acid deficiency state.

### ADVERSE EFFECTS :

Headache, Rash, Diarrhoea, Blood disorders, Pain in the muscles (myalgia), Seizures (convulsions), Nausea and vomiting, Severe blistering skin reaction affecting the tissues of the eyes, mouth, throat and genitals (Stevens-Johnson Syndrome), Inflammation of the lining of the mouth (stomatitis), Damage to the liver, Damage to the kidneys.

### PRECAUTIONS :

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 (G6PD deficiency)

### WARNINGS :

Erythema multiforme, toxic epidermal necrolysis and allergic vasculitis may occur.

### DOSAGE & ADMINISTRATION :

*Usual Dosage ; Adults :* 960mg every 12 hrs increased to 1.44g in severe infections. 480mg every 12 hrs if treated for more than 14 days.

*Children 6-12 years :* 480mg;