### 1.6.1.1 Name of the medicinal Product

Paediatric Co-trimoxazole Tablets BP

#### 1.6.1.1.1 Strength

100 mg + 20 mg

#### 1.6.1.1.2 Pharmaceutical Form

Oral Tablet

### 1.6.1.2 Qualitative and Quantitative Composition

#### 1.6.1.2.1 Qualitative declaration

Sulfamethoxazole BP

Trimethoprim BP

#### 1.6.1.2.2 Quantitative declaration

| Sr. No. | Ingredients Chemical Name | Specification | Standard Quantity/ Tablet (mg) | Reason for Inclusion |
|---|---|---|---|---|
| 01 | Sulfamethoxazole | BP | 100.00 | Antibacterial |
| 02 | Trimethoprim | BP | 20.00 | Antibacerial |
| 03 | Maize Starch | BP | 130.70 | Diluent |
| 04 | Maize Starch * | BP | 19.350 | Binder |
| 05 | Sodium Methyl Hydroxybenzoate | BP | 0.300 | Antimicrobial Preservative |
| 06 | Sodium Propyl Hydroxybenzoate | BP | 0.150 | Antimicrobial Preservative |
| 07 | Purified Water | BP | Q.S. | Binding Solvent |
| 08 | Magnesium Stearate | BP | 5.000 | Lubricant |

| Sr. No. | Ingredients Chemical Name | Specification | Standard Quantity/ Tablet (mg) | Reason for Inclusion |
|---|---|---|---|---|
| 09 | Purified Talc | BP | 10.00 | Glidant |
| 10 | Sodium Starch Glycolate (Type-A) | BP | 5.000 | Disintegrant |

**1.6.1.3 Pharmaceutical Form**

Oral Tablet

White to colour, round shaped, flat, uncoated tablets, breakline on one side and plain on other side.

**1.6.1.4 Clinical Particulars**

**1.6.1.4.1 Therapeutic 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.

**1.6.1.4.2 Posology and Method of Administration**

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

Children 6-12 years: 480 mg;

6 months to 5 yrs. : 240 mg;

6 weeks to 5 months: 120 mg.

All doses should be given every 12 hrs.

Prophylaxis of recurrent urinary tract infection:

Adults: 480 mg at night.

Children: 6-12mg/kg body weight at night.

Gonorrhoes:

Adults: 1.92 g every 12 hrs for 2 days, or 2.4 g followed by a further dose of 2.4 g after 8 hrs.

High-Dose Therapy for pneumocystis carinii infections: 120 mg/kg daily in 2-4 divided doses for 14 days.

The dosage must be reduced in patients with renal insufficiency and the preparation should not be administered if the creatinine clearance rate is leas than 15 mL/minute.

Frequent haematological investigations are required during prolonged therapy.

**1.6.1.4.3 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 B12, and folic acid deficiency state.

**1.6.1.4.4 Special Warnings and Special Precautions for Use**

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)

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

**1.6.1.4.5 Interaction with other medicinal products and other forms of interaction**

Cyclosporine: May cause decrease in therapeutic effect of cyclosporine and increased risk of nephrotoxicity.

Methotrexate : May displace methotrexate from protein-binding sites, thus increasing free methotrexate levels.

Phenytoin: Trimethoprim may inhibit metabolism of phenytoin or other hydantoins.

Procalnamide: Trimethoprim may be inhibit renal elimination of procainamide and its metabolites.

Sulfonylureas: May increase hypoglycemic response to sulfonylureas because of displacement from protein binding sites or inhibition of hepatic metabolism.