

Cefpodoxime Proxetil USP Capsule / Powder for Suspension / Paediatric Drops

## DESCRIPTION

Starin® is a preparation of Cefpodoxime Proxetil, which is a prodrug. Its active metabolite, Cefpodoxime, is an extended spectrum, semi-synthetic antibiotic of the third generation cephalosporin class. It is active against both Gram-positive and Gram-negative bacteria. It is highly stable in the presence of beta-lactamase enzymes.

#### INDICATIONS

• Upper respiratory tract infections • Lower respiratory tract infections (including bronchitis and pneumonia) • Skin and soft tissue infections • Uncomplicated urinary tract infections • Uncomplicated gonorrhoea • Gynaecological infections • Acute otitis media • Childhood infections

## DOSAGE AND ADMINISTRATION

## Adult

- Upper respiratory tract infections (but in pharyngitis and tonsillitis reserved for infections which are recurrent, chronic, or resistant to other antibacterial): 100 mg twice daily (in sinusitis 200 mg twice daily)
- Lower respiratory tract infections (including bronchitis and pneumonia): 100 to 200 mg twice daily
- . Skin and soft tissue infections: 200 mg twice daily
- . Uncomplicated urinary tract infections: 100 mg twice daily
- Uncomplicated upper urinary tract infections: 200 mg twice daily
- Uncomplicated gonorrhoea: 200 mg as a single dose

## Children

• 15 days to 6 months: 4 mg/kg every 12 hours • 6 months to 2 years: 40 mg every 12 hours • 3 to 8 years: 80 mg every 12 hours

• Over 9 years: 100 mg every 12 hours

## CONTRAINDICATIONS

Hypersensitivity to cefpodoxime or to the cephalosporin group of antibiotics. It is contraindicated in patients with porphyria.

#### **USE IN PREGNANCY & LACTATION**

Pregnant women: There are no adequate and well-controlled studies of Cefpodoxime Proxetil use in pregnant women. Cefpodoxime may be administered to pregnant women only if clearly indicated.

Lactating mother: Cefpodoxime is excreted in breast milk. So, patients taking this drug should not breast-feed

#### PRECAUTIONS

Penicillin sensitivity, in case of mild renal impairment dose should be reduced.

#### DRUG INTERACTIONS

Antacid and histamine H<sub>2</sub>-antagonists reduce absorption of Cefpodoxime. Loop diuretics may increase nephrotoxicity of cephalosporins.

#### SIDE-FFFFCTS

Diarrhoea and rarely antibiotic associated colitis, nausea and vomiting, abdominal discomfort, headache, allergic reactions including rashes, pruritus, urticaria, serum sickness-like reactions with rashes, fever and arthralgia, anaphylaxis, arrhythmia multiforme, toxic epidermal necrolysis reported; disturbances in liver enzymes, transient hepatitis and cholestatic iaundice.

## PHARMACEUTICAL PRECAUTION

Capsule: Do not store above 30 °C temperature. Keep away from light and wet place.

**Powder for Suspension:** Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of the reach of children.

#### PACKAGING

### Starin® 100 Cansule:

Box containing 4 strips of 4 capsules each. Each capsule contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 100 mg.

## Starin® Powder for Suspension:

Bottle containing powder for the preparation of 50 mL suspension. After reconstitution each 5 mL contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 40 mg.

## Starin® DS Powder for Suspension:

Bottle containing powder for the preparation of 50 mL suspension. After reconstitution each 5 mL contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 80 mg.

## Starin® Powder for Paediatric Drops:

Bottle containing powder for the preparation of 15 mL suspension. After reconstitution each mL contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 20 mg.

# SK+F

Manufactured by **ESKAYEF PHARMACEUTICALS LTD.** 

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