

SOLODOXIM Suspension

(C e f p o d o x i m e U S P)

سولوڈوکسیم سسپینشن
(سینٹپوڈوکسیم یو ایس پی)

COMPOSITION:

Solodoxim Suspension 40mg/5ml

Each 5ml after reconstitution contains:

Cefpodoxime proxetil (USP) eq. to Cefpodoxime.....40mg

Solodoxim Suspension 100mg/5ml

Each 5ml after reconstitution contains:

Cefpodoxime proxetil (USP) eq. to Cefpodoxime.....100mg

Product complies USP specs.

DESCRIPTION:

Cefpodoxime is an oral third generation cephalosporin antibiotic with effectiveness against most Gram positive and Gram negative bacteria.

MECHANISM OF ACTION:

Like other β -lactam drugs, cefpodoxime exerts antibacterial activity by binding to and inhibiting the action of certain bacterial cell wall synthetic enzymes, namely the penicillin binding proteins. This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

INDICATIONS:

SOLODOXIM is indicated for the treatment of the following infections when caused by susceptible organisms.

- Acute otitis media
- Sinusitis
- Tonsillitis and pharyngitis

Note: "In these indications, Cefpodoxime should be reserved for recurrent or chronic infections, or for infections where the causative organism is known or suspected to be resistant to commonly used antibiotics or in case the commonly used antibiotic cannot be used for any reason"

- Acute bronchitis
- Bacterial pneumonia

Cefpodoxime is not the preferred antibiotic for the treatment of staphylococcal pneumonia and should not be used in the treatment of atypical pneumonia caused by organisms such as Legionella, Mycoplasma and Chlamydia.

DOSAGE & ADMINISTRATION:

Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis

200 mg orally every 12 hours for 10 days

Sinusitis

Infants under 2 months: safety and efficacy not established
Infants 2 months – Children 12 years: 5 mg/kg orally every 12

hours for 10 days; individual doses not to exceed 200 mg.
Children over 12 years: 200 mg orally every 12 hours for 10 days

Pharyngitis/Tonsillitis

Infants under 2 months: safety and efficacy not established
Infants 2 months – Children 12 years: 5 mg/kg orally every 12 hours for 5-10 days; individual doses not to exceed 100 mg
Children over 12 years: 100 mg orally every 12 hours for 5-10 days

Acute Otitis Media

Infants under 2 months: safety and efficacy not established
Infants 2 months – Children 12 years: 5 mg/kg orally every 12 hours for 5 days, individual doses not to exceed 200 mg
Children over 12 years: 200 mg orally every 12 hours for 5 days

Dosing Modifications

Renal impairment

Creatinine

- clearance under 30 ml/min: give every 24 hours
- Hemodialysis: give 3 times weekly after dialysis

Hepatic impairment

- Dosage adjustment not necessary.

DIRECTIONS FOR RECONSTITUTION:

To make 50ml suspension, add 40ml freshly boiled and cooled water to the granules by using given measuring cup and shake well to dissolve the granules.

PHARMACOKINETICS:

Cefpodoxime proxetil is taken up in the intestine and is hydrolysed to the active metabolite cefpodoxime. When cefpodoxime proxetil is administered orally, 51.1% is absorbed and absorption is increased by food intake. The volume of distribution is 32.31 and peak levels of cefpodoxime occur 2 to 3 hours after dosing.

The maximum plasma concentration is 1.2 mg/L and 2.5 mg/L after doses of 100 mg and 200 mg respectively. The main route of excretion is renal, 80% is excreted unchanged in the urine with an elimination half-life of approximately 2.4 hours.

SIDE EFFECT:

Following side effects may occur:

Localized abdominal pain, abdominal cramp, headache, generalized abdominal pain, asthenia, fever, fungal infection. Nausea, anorexia, dry mouth, stomatitis, thrombocytopenia, positive direct Coombs test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time,

thrombocytopenic purpura, increased SGPT, myalgia, hallucination, hyperkinesia, nervousness, epistaxis, rhinitis, urticaria, fungal dermatitis, acne, increase in BUN and creatinine. Most of these abnormalities were transient and not clinically significant.

PRECAUTIONS:

Hypersensitivity reactions

Cefpodoxime is contraindicated in patients who have had a previous hypersensitivity reaction to any cephalosporin. It is also contraindicated in patients who have had a previous immediate and /or any severe hypersensitivity reaction to any penicillin or to any other betalactam drug..

Renal Insufficiency

In cases of severe renal insufficiency it may be necessary to reduce the dose dependent on the creatinine clearance.

Gastrointestinal disease

Cefpodoxime should always be used with caution in patients with a history of gastrointestinal disease, particularly colitis. Antibiotic associated diarrhoea, colitis and pseudomembranous colitis have been reported with the use of cefpodoxime.

Blood monitoring

As with all beta-lactam antibiotics, neutropenia and more rarely agranulocytosis may develop particularly during extended treatment.

Prolonged use

As with other antibiotics, the prolonged use of cefpodoxime proxetil may result in the overgrowth of non-susceptible organisms. With oral antibiotics the normal colonic flora may be altered, allowing overgrowth by clostridia with consequent pseudomembranous colitis. Repeated evaluation of the patient is essential and if superinfection occurs during therapy, appropriate measures should be taken.

DRUG INTERACTIONS:

Histamine H2-antagonists and antacids reduce the bioavailability of cefpodoxime.

Probenecid reduces the excretion of cephalosporins.

Cephalosporins potentially enhance the anticoagulant effect of coumarins and reduce the contraceptive effect of estrogens.

Influence On Laboratory Diagnostic Tests A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.

CONTRAINDICATIONS:

Hypersensitivity to the active substance, to any of the cephalosporins or to any of the excipients. Previous immediate and/or severe hypersensitivity reaction to a penicillin or to any other type of beta-lactam drug.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

Solodoxim Suspension 40mg/5ml

50ml

Solodoxim Suspension 100mg/5ml

50ml

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے

درمیان رکھیں۔ دھوپ، گرمی، نمی سے محفوظ اور

بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر

کے نسخے پر فروخت کریں۔

Manufactured by:

**PHARMASOL
PRIVATE LIMITED**

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.