

Cefix

(Cefixime) USP

CAPSULES

SUSPENSION

PRESENTATION

CEFIX CAPSULES

Cefix capsule 200mg:

Each capsule contains Cefixime (as trihydrate) USP.....200mg

Cefix capsule 400mg:

Each capsule contains Cefixime (as trihydrate) USP.....400mg

CEFIX SUSPENSION

Cefix 30ml & 60ml Suspension

Each 5ml of reconstituted suspension contains:

Cefixime (as trihydrate) USP.....100mg

Cefix DS Suspension 30ml

Each 5ml of reconstituted suspension contains:

Cefixime (as trihydrate) USP.....200mg

INDICATIONS

Cefix (Cefixime) is an orally cephalosporin antibiotic, which has marked in-vitro bactericidal activity against a wide variety of Gram positive & Gram negative organisms. It is indicated for the treatment of the following acute infections when caused by susceptible micro organisms.

- Upper respiratory tract infections (URTI): e.g. Otitis media, sinusitis, pharyngitis & tonsillitis.
- Lower respiratory tract infections (LRTI): e.g. Bronchitis.
- Urinary tract infections (UTI): e.g. Cystitis, cystourethritis, uncomplicated pyelonephritis & uncomplicated gonorrhoea.

IN VITRO ACTIVITY

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Escherichia coli*, *Proteus mirabilis*, *Klebsiella* species, *Haemophilus influenzae* (beta-lactamase positive & negative) & *Enterobacter* species. **Cefix** (Cefixime) is highly stable in the presence of beta-lactamase enzymes. **Cefix** (Cefixime) has been shown to be active in vitro against most strains of the following organisms; however, clinical efficacy has been established. *Streptococcus agalactiae*, *Haemophilus parainfluenzae* (beta-lactamase positive & negative strains), *Proteus vulgaris*, *Pasteurella multocida* (P. septic), *Providencia* species, *Salmonella* species, *Shigella* species, *Citrobacter diversus* & *Serratia marcescens*.

DOSAGE & ADMINISTRATION

Absorption of **Cefix** (Cefixime) is not significantly modified by the presence of food. The usual course of treatment is 5-14 days.

ADULTS & CHILDREN OVER 12 YEARS: The recommended adult dose is 400mg one capsule daily.

CHILDREN: Dose for children is 8mg/kg/day once daily. As a general guide for prescribing in children, the following daily doses in terms of volume of Paediatric Oral suspension are suggested.

CHILDREN 1-4 YEARS: 5ml daily (1 teaspoonful).

CHILDREN 5-9 YEARS: 10ml daily (2 teaspoonful).

CHILDREN 10-12 YEARS: 15ml daily (3 teaspoonful).

The dosage in children aged 6 months to one year should be calculated on mg/kg basis. Children weighing more than 30 kg or older than 12 years should be treated with the recommended adult dose. The safety & efficacy of **Cefix** (Cefixime) has not been established in children aged less than 6 months.

THE ELDERLY: Elderly Patients may be given the same dose as recommended for adults. Renal function should be assessed & dosages should be adjusted in severe renal impairment.

DOSAGE IN RENAL IMPAIRMENT

Cefix (Cefixime) may be administered in the presence of impaired renal function. Normal dose may be given to patients with creatinine clearance 20ml/min or greater. In patients whose creatinine clearance is less than 20ml/min, it is recommended that a dose of 200mg once daily should not be exceeded. The dialysis or haemodialysis should follow the same recommendation as that for patients with creatinine clearances less than 20ml/min.

CONTRA INDICATION

Patients with known hypersensitivity to cephalosporin antibiotics.

PRECAUTIONS & WARNING

Cefix (Cefixime) should not be given to patients who have shown hypersensitivity to other drugs. Cephalosporins would be given with caution to penicillin-sensitive patients, as there is some evidence of partial cross allergenicity between the penicillin and the cephalosporins. If an allergic effect occurs with **Cefix** (Cefixime) the drug should be discontinued. Treatment with broad-spectrum antibiotics alter the normal flora of the Colon and may permit overgrowth of Clostridia. Studies indicate that toxin produced by *Clostridium difficile* is a primary cause of antibiotic-associated diarrhea. Pseudomembranous colitis is associated with the use of broad-spectrum antibiotics (including macrolide, semi-synthetics penicillin, lincosamides and cephalosporins; it is therefore important to consider its diagnosis on patients who develop diarrhoea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment.

USE IN PREGNANCY AND BREAST FEEDING

Reproduction studies have been performed in mice rats at doses up to 400 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to **Cefix** (Cefixime). There are no adequate and well controlled studies in pregnant women.

Therefore **Cefix** (Cefixime) should not be used in pregnancy or in nursing mothers unless considered essential by the physician.

INTERACTIONS

No significant drug interactions have been reported to date. A false positive reaction for glucose in the urine may occur with Benedicts or Fehlings solutions or with copper sulphate test tables but not with tests based on enzymatic glucose oxidates reactions. A false positive direct Coombs test has been reported during treatment with cephalosporins antibiotics, therefore it should be recognized that a positive Coombs test may due to the drug.

OVERDOSE

There is no experience with overdoses **Cefix** (Cefixime). Adverse reactions seen at dose levels up to 2g **Cefix** (Cefixime) in normal subjects did not

differ from the profile seen in patients treated at the recommended doses.
Cefix (Cefixime) is not removed from the circulation in significant quantities by dialysis.

SIDE EFFECTS

Cefix (Cefixime) is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self limiting in nature.

G.I. SYSTEM

The most frequent side effect seen with **Cefix** (Cefixime) is diarrhoea. Some cases of moderate to severe diarrhoea have been reported: this has occasionally warranted cessation of therapy. **Cefix** (Cefixime) should be discontinued if marked diarrhoea occurs. Other gastrointestinal side effects seen less frequently are nausea, abdominal pain, dyspepsia vomiting and flatulence. Pseudomembranous colitis has been reported.

CENTRAL NERVOUS SYSTEM

Headache and dizziness.

HYPERSENSITIVITY REACTIONS

Allergies in the form of rash, pruritus, urticaria, drug fever and arthralgia have been observed. These reactions usually subsided on discontinuation of therapy.

HEMATOLOGICAL AND CLINICAL CHEMISTRY

Thrombocytopenia, leukopenia and eosinophilia have been reported. These reactions were infrequent and reversible. Mild transient changes in liver and renal function tests have been observed.

MISCELLANEOUS

Other possible reactions include genital pruritus and vaginitis.

Directions for reconstitution:

To make 60ml Cefix Suspension:

Tap the bottle several times to loosen powder prior to reconstitution. Add **20ml** of previously boiled cool water using enclosed cup and shake well. Again add **20ml** previously boiled cool water in it and shake well to make **60ml** suspension.

To make 30ml Cefix / Cefix-DS Suspension:

Tap the bottle several times to loosen powder prior to reconstitution. Add **10ml** of previously boiled cool water using enclosed cup and shake well. Again add **10ml** previously boiled cool water in it and shake well to make **30ml** suspension.

To make 15ml Cefix / Cefix-DS Suspension:

Tap the bottle several times to loosen powder prior to reconstitution. Add **10ml** of previously boiled cool water using enclosed cup and shake well to make **15ml** suspension.

NOTE:

When reconstituted, store in a refrigerator & consume within 14 days. Discard any unused portion after 14 days.

INSTRUCTIONS

Store below 30°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION CEFIX CAPSULES

Cefix 200mg & 400mg Capsules:

Available in Alu-Alu packing of 5 capsules.

CEFIX SUSPENSION

Cefix 30ml Suspension

Bottle containing fine powder for preparation of 30ml suspension.

Cefix 60ml Suspension

Bottle containing fine powder for preparation of 60ml suspension.

Cefix DS Suspension 30ml

Bottle containing fine powder for preparation of 30ml DS suspension.

سیفکس / سیپول / سیفکسین

(سیفکسیمائڈ) ہائپسین

دوا تیار کرنے کا طریقہ:

سیفکس 60 لیٹر سیفکسین تیار کرنے کا طریقہ:

سیفکسین بنانے کے لئے بوتل کو اچھی طرح ہلایے تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب ڈبے میں موجود کپ سے ٹاپ کر **20** ملی لیٹر پیپلے سے اُٹا ہوا خنڈرا پانی شامل کیجئے اور اچھی طرح ہلایے۔ پھر مزید **20** ملی لیٹر پیپلے سے اُٹا ہوا خنڈرا پانی شامل کیجئے اور اچھی طرح ہلایے تاکہ **60** ملی لیٹر سیفکسین تیار ہو جائے۔

سیفکس / سیفکس (ڈی ایس) 30 ملی لیٹر سیفکسین تیار کرنے کا طریقہ:

سیفکسین بنانے کے لئے بوتل کو اچھی طرح ہلایے تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب ڈبے میں موجود کپ سے ٹاپ کر **10** ملی لیٹر پیپلے سے اُٹا ہوا خنڈرا پانی شامل کیجئے اور اچھی طرح ہلایے۔ پھر مزید **10** ملی لیٹر پیپلے سے اُٹا ہوا خنڈرا پانی شامل کیجئے اور اچھی طرح ہلایے تاکہ **30** ملی لیٹر سیفکسین تیار ہو جائے۔

سیفکس / سیفکس (ڈی ایس) 15 ملی لیٹر سیفکسین تیار کرنے کا طریقہ:

سیفکسین بنانے کے لئے بوتل کو اچھی طرح ہلایے تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب ڈبے میں موجود کپ سے ٹاپ کر **10** ملی لیٹر پیپلے سے اُٹا ہوا خنڈرا پانی شامل کیجئے اور دھنن لگا کر اچھی طرح ہلایے تاکہ **15** ملی لیٹر سیفکسین تیار ہو جائے۔

خود کار کا شیڈول			
1 سے 4 سال	1	30 ملی لیٹر اور 60 ملی لیٹر سیفکسین کیلئے	30 ملی لیٹر ڈی ایس سیفکسین کیلئے
1 سے 4 سال	1	چائے کا چمچ (2.5) ملی لیٹر (دن میں ایک مرتبہ)	1/2 چائے کا چمچ (2.5) ملی لیٹر (دن میں ایک مرتبہ)
5 سے 9 سال	2	چائے کے چمچ (5) ملی لیٹر (دن میں ایک مرتبہ)	1 چائے کا چمچ (5) ملی لیٹر (دن میں ایک مرتبہ)
10 سے 12 سال	3	چائے کے چمچ (7.5) ملی لیٹر (دن میں ایک مرتبہ)	1 1/2 چائے کا چمچ (7.5) ملی لیٹر (دن میں ایک مرتبہ)
12 سال سے زائد کیلئے	2 چائے کے چمچ (10) ملی لیٹر (دن میں ایک مرتبہ)	2 چائے کے چمچ (10) ملی لیٹر (دن میں ایک مرتبہ)

یاڈ آکر کی ہدایت کے مطابق استعمال کریں

دوا کو **30** ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیے۔ تمام دوا میں بچوں کی تیق سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کیجئے۔ استعمال سے پہلے بوتل کو اچھی طرح ہلایے۔



Manufactured by:
STANDPHARM PAKISTAN (PVT) LTD
20 Km Ferozepur Road Lahore, Pakistan.
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