

DIRECTIONS FOR PREPARATION:

Suspension for 30 ml:

To reconstitute 30ml suspension from provided sterile water. Twist the cap of plastic ampoule to detach. Add half (10ml) water to the contents present in bottle, invert and shake to the wet powder, then add remaining half (10ml) water and shake well to make homogeneous suspension. **Reconstituted suspension should be used within 14 days.**

Suspension for 15ml:

To reconstitute 15ml suspension from provided sterile water. Twist the cap of plastic ampoule to detach. Add half (5ml) water to the contents present in bottle, invert and shake to the wet powder, then add remaining half (5ml) water and shake well to make homogeneous suspension. **Reconstituted suspension should be used within 14 days.**

PACKAGE QUANTITY: (Dry Suspension & Capsules)

Granules for Paediatric Oral Suspension (100 mg / 5 ml and 200 mg / 5 ml after reconstitution): 60 ml bottle containing granules for preparation of 30 ml suspension.
Ceftas 200 mg & 400 mg Capsules are supplied in pack of 5's.

Store below 30°C in a dry place, protect from light.

For oral use only.

Keep bottle tightly closed.

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

Keep out of the reach of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں، روشنی سے بچائیں۔
استعمال صرف پینے کے لئے استعمال کریں۔
استعمال کے بعد دھکن کو اچھی طرح بند کریں۔
صرف رتھڑا ڈاکٹر کے نسخے پر فروخت کریں۔
تیار شدہ سسپنشن ۱۴ دن تک قابل استعمال ہے۔
بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

Platinum
Pharmaceuticals (Pvt) Ltd.

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Mfg. Lic. No. 000415

QAR No.AW22-1034-02

Ceftas Suspension
(Cefixime) سسپنشن

Ceftas DS Suspension
(Cefixime) سسپنشن

Ceftas 200 mg Capsules
(Cefixime) کپسولز

Ceftas 400 mg Capsules
(Cefixime) کپسولز

COMPOSITIONS:

Ceftas Suspension 100mg / 5ml
Each 5ml contains:
Cefixime Trihydrate eq. to Cefixime
Anhydrous 100mg
Product Complies U.S.P. Specs

Ceftas DS Suspension 200mg / 5ml
Each 5ml contains:
Cefixime Trihydrate eq. to Cefixime
Anhydrous 200mg
Product Complies U.S.P. Specs

Ceftas Capsules 200mg
Each capsule contains:
Cefixime Trihydrate eq. to Cefixime
Anhydrous 200mg
Product Complies J.P. Specs

Ceftas Capsules 400mg
Each capsule contains:
Cefixime Trihydrate eq. to Cefixime
Anhydrous 400mg
Product Complies J.P. Specs

INDICATIONS:

Ceftas is indicated in the treatment of the following infections caused by the following micro-organisms susceptible to Ceftas.

Microorganisms

Streptococcus sp.
Streptococcus pneumoniae
Neisseria gonorrhoeae
Neisseria meningitidis
Moraxella (Branhamella) catarrhalis
Escherichia coli
Klebsiella sp.
Serratia sp.
Proteus sp.
Providencia sp.
Morganella morganii
Haemophilus influenzae
Haemophilus parainfluenzae
Salmonella sp.
Shigella sp.
Aeromonas hydrophila
Pasteurella multocida
Citrobacter freundii
Citrobacter amalonaticus
Citrobacter diversus
Enterobacter sp.
Acinetobacter Iwoffi
Yersinia enterocolitica
Campylobacter jejuni

INFECTIONS

Respiratory Tract Infections

- Infection of the upper and lower airways
- Pulmonary infections of bacterial etiology
- Bronchitis (acute, chronic)
- Pneumonia
- Bronchiectasis with infection
- Secondary infections in chronic respiratory diseases

Ear Nose and Throat Infections

- Otitis media
- Sinusitis
- Tonsillitis
- Pharyngitis
- Laryngitis

Gastrointestinal Infections

- Typhoid

Urinary Tract Infections

- Infections of the kidneys and efferent urinary tract
- Complicated and uncomplicated urinary tract infections except for prostatitis
- Pyelonephritis
- Cystitis
- Gonococcal urethritis
- Uncomplicated gonorrhoea (cervical/urethral)

Biliary Tract Infections

- Infections of the biliary tract
- Cholecystitis
- Cholangitis

SCARLET FEVER

DOSAGE & ADMINISTRATION:

Absorption of 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 dosage is 400 mg daily administered as single dose.

Children (Use paediatric Oral Suspension):

The recommended dosage for children is 8 mg / kg / day administered as a single dose. As a general guide for prescribing in children, the following daily doses in terms of volume of Paediatric Oral Suspension are suggested.

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 and efficacy of Cefixime has not been established in children aged less than 6 months.

Paediatric Oral Suspension	
Children 1-4 years	: 5 ml daily
Children 5-9 years	: 10 ml daily
Children 10-12 years	: 15 ml daily

DS Oral Suspension	
Children 1-4 years	: 2.5 ml daily
Children 5-9 years	: 5 ml daily
Children 10-12 years	: 7.5 ml daily
Adult & Children over 12 years	: 10 ml daily

The elderly

Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed and dosage should be adjusted in severe renal impairment.

DOSAGE IN RENAL IMPAIRMENT

Cefixime may be administered in the presence of impaired renal function. Normal dose and frequency may be given in patients with creatinine clearance of 20 ml / min or greater. In patients whose

creatinine clearance is less than 20 ml / min, it is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemodialysis should follow the same recommendation as that for patients with creatinine clearance of less than 20 ml/min.

CONTRAINDICATIONS:

Patients with known allergy to the Cephalosporin group of antibiotics.

PRECAUTIONS & WARNINGS:

- As a general rule, the duration of treatment with this drug should be limited to a minimum period required for the treatment of the patient's condition, after susceptibility of the micro-organism to the drug has been confirmed, in order to prevent the emergence of drug-resistant micro-organisms.
- Careful inquiry should be made to determine whether the patient has had previous hypersensitivity to cephalosporins, penicillins or other drugs.
- Particular care should be exercised in patients with a personal or familial predisposition to allergic reactions such as bronchial asthma, rash or urticaria.
- Particular care should be exercised in patients with severe gastrointestinal disturbances involving vomiting and diarrhea.
- Particular care should be exercised in patients with severely impaired renal function, patients with poor oral nutrition, patients receiving parenteral nutrition, elderly patients or patients in a debilitated state.
- Renal function should be monitored with particular care when combining cefixime with an aminoglycoside antibiotic, polymyxin B, colistin or high-dose loop diuretics (e.g. furosemide). This is applied especially to patients with pre existing renal impairment.
- Adverse reactions to drugs are liable to occur more frequently in the elderly patients since they usually have physiological hypofunction.
- Bleeding tendency due to Vitamin K deficiency may occur in the elderly.

USE IN PREGNANCY AND BREAST FEEDING:

Like other cephalosporins, Cefixime is included in therapeutic category B of FDA for use in pregnancy. Reproduction studies have been performed in mice and rats at doses up to 400 times the human dose and have revealed no evidence of harm to the fetus due to cefixime.

Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

DRUG INTERACTIONS

A prolonged prothrombin time has been reported in patients who had been administered cefixime and anticoagulants of the coumarin-type.

OVER DOSAGE

There have been limited clinical experiences with overdose of cefixime to date.

ADVERSE REACTIONS

Anaphylactic reaction including shock, internal swelling of the larynx with airways constriction Fever, Stevens-Johnson syndrome.

Rash, Erythema (Erythema multiforme), Pruritus, Leukopenia, Eosinophilia, Thrombocytopenia

Increases in GOT, GPT and alkaline phosphatases.

Serious colitis (such as pseudomembranous colitis), Diarrhoea, Abdominal pain, Vomiting, Nausea

Transient elevation in BUN or creatinine

Headache, Dizziness