iCef

(Cefixime USP)

آئیسیف

کیپسولز / سسپینشن / ڈی ایس سسپینشن

(سیفیکزیم یو ایس پی)

Capsules/Suspension/DS Suspension

Presentation:

ICEF capsules 200mg:
Each hard gelatin capsule contains Cefixime as trihydrate(USP) ..... 200mg.

ICEF capsules 400mg:
Each hard gelatin capsule contains Cefixime as trihydrate(USP) ..... 400mg.

Granules for paediatric oral suspension:
ICEF fine granules contain 100mg of Cefixime USP in each 5 ml volume of reconstituted tutti-frutti flavoured suspension.

Granules for DS Oral Suspension:
ICEF fine granules contain 200mg of Cefixime USP in each 5ml volume of reconstituted tutti-frutti flavoured suspension.

INDICATIONS:

ICEF is indicated in the treatment of the following infections caused by the following microorganisms susceptible to Cefixime.

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 lwoffi
- Yersinia enterocolitica
- Campylobactar jejuni

INFECTIONS

RESPIRATORY TRACT INFECTIONS

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

DIRECTIONS FOR RECONSTITUTION:

Please see carton for reconstitution of granules for Paediatric Oral Suspension and DS Oral Suspension.

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
- Uncomplicated urinary tract infection
- Complicated and uncomplicated urinary tract infections except for prostatitis
- Pyelonephritis
- Cystitis
- Gonococcal urethritis
- Uncomplicated gonorrhea (cervical/urethral)

BILIARY TRACT INFECTIONS:

- Infections of the biliary tract
- Cholecystitis
- Cholangitis

SCARLET FEVER

DOSAGE AND ADMINISTRATION:

Absorption of ICEF is not significantly modified by the presence of food. The usual course of treatment is 5-14 days.

Adults and children over 12 years:

The recommended adult dosage is 400mg daily administered as single dose.

Children (use paediatric Oral Suspension or DS Oral Suspension):

The recommended dosage for children is 8mg/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 or DS Oral Suspension are suggested.

Paediatric Oral Suspension		DS Oral Suspension	
Children 1-4 years	: 5 ml daily	Children 1-4 years	: 2.5 ml daily
Children 5-9 years	: 10 ml daily	Children 5-9 years	: 5 ml daily
Children 10-12 years	: 15 ml daily	Children 10-12 years	: 7.5 ml daily
		Adults & Children over 12 years	: 10 ml daily

The dosage in children aged 6 months to one year should be calculated on mg/kg basis, Children weighing more than 30kg 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.

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:

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

CONTRAINDICATIONS:

Patients with known allergy to the Cephalosporin group of antibiotics.

PRECAUTIONS AND 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 reaction such as bronchial asthma, rash or urticaria.
- Particular care should be exercised in patients with severe gastrointestinal disturbances involving vomiting and diarrhoea.
- Particular care should be exercised in patients with severly 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-dosed loop diuretics (e.g. furosemide). This is applied specially 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, ICEF is included in therapeutic category B of FDA for use in pregnancy. Reproduction studies have been performed in mice and rats at doses upto 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.

OVERDOSAGE:

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

PHARMACEUTICAL PRECAUTIONS:

Store below 30°C. Shake well before use.
Protect from moisture, excessive heat, sunlight and freezing.
To be sold on the prescription of a registered medical practitioner only.

PACKAGE QUANTITIES:

Capsules 200mg: 1 strip of 5 capsules.

Capsules 400mg: 1 strip of 5 capsules.

Granules for Paediatric Oral Suspension (100mg/5ml after reconstitution):
30ml bottle containing granules for preparation of 30ml suspension.

Granules for DS Oral Suspension (200mg/5ml after reconstitution):
30ml bottle containing granules for preparation of 30ml suspension.

Use only on medical advice.
Keep out of reach of children.
For oral use only.

خوراک اور طریقہ استعمال:

بالغان اور ۱۲ سال سے بڑے بچوں کیلئے:
کیپسول: ۴۰۰ ملی گرام روزانہ
یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

۱۲ سال سے کم عمر کے بچوں کیلئے:
۸ ملی گرام فی کلوگرام فی ۲۴ گھنٹے بطور ایک خوراک
یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
استعمال سے پہلے بوتل کو اچھی طرح ہلا لیں۔
نمی، حرارت، دھوپ اور منجمد ہونے سے بچائیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر ہی فروخت کریں۔
سسپینشن بنانے کا طریقہ کارٹن پر درج ہے۔
سسپینشن بنانے کے بعد ایک ہفتہ تک استعمال کیا جا سکتا ہے۔

عمومی خوراک برائے پیڈیاٹرک سسپینشن

عمر	روزانہ بطور ایک خوراک
۱ سے ۴ سال	۵ ملی لیٹر
۵ سے ۹ سال	۱۰ ملی لیٹر
۱۰ سے ۱۲ سال	۱۵ ملی لیٹر

عمومی خوراک برائے ڈی ایس سسپینشن

عمر	روزانہ بطور خوراک
۱ سے ۴ سال	۲٫۵ ملی لیٹر
۵ سے ۹ سال	۵ ملی لیٹر
۱۰ سے ۱۲ سال	۷٫۵ ملی لیٹر
بالغ اور ۱۲ سال سے بڑے	۱۰ ملی لیٹر

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