KURACEF™

Cefixim Trihydrate BP

50011

SANOFI

PRESENTATION:

Kuracef 200 tablet: Octagonal shape and light pink colored tablet; each tablet contains cefeixime trihydrate BP equivalent to 200mg cefixime.

Kuracef 400 tablet: Octagonal shape and light pink colored tablet; each tablet contains cefeixime trihydrate BP equivalent to 400 mg cefixime.

Kuracef 30ml or 50ml suspension: Bottles containing powder for preparation of 30ml or 50ml of light yellow colored, banana flavoured suspension; when reconstituted each 5 ml contains cefixime trihydrate BP equivalent to 100mg Cefixime.

INDICATION:

Kuracef is indicated in the treatment of the following infections when caused by susceptible bacteria-

Upper Respiratory Tract Infections: e.g. otitis media, pharyngitis, tonsillitis.

Lower Respiratory Tract Infection: e.g. bronchitis.

Urinary Tract Infections: e.g. cystitis, cystourethritis, uncomplicated pyelonephritis, urethritis, acute uncomplicated gonorrhea.

Others: e.g. skin infection, secondary infection in trauma, burn or surgical wound, cholangitis.

DOSAGE & ADMINISTRATION

Adult and child over 10 years, 200-400 mg daily according to the severity of infection, gave either in single or 2 divided doses. 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. Child over 6 months 8mg/kg daily in single or 2 divided doses or as general guide of dosage may be given as following-

6 months to 1 year 75mg daily; 1-4 years 100mg daily; 5-10 years 200mg daily. In typhoid dosage should be 10mg/kg/day for 14 days.

The usual course of treatment is 7 days. This may be continued up to 14 days as in typhoid or in any severe infection if the physicians desire.

Cefixime may be administered in the presence of impaired renal function as per following dosage schedule:

Creatinine Clearance (ml/min)	Dosage
>60	Standard
21 to 60 or renal hemodialysis	75% Standard
≤20 or continuous ambulatory peritoneal dialysis	50% Standard

CONTRAINDICATIONS

Known hypersensitivity to cefixime or to an antibiotic from the cephalosporin group, or to any of the excipients.

WARNINGS

Severe cutaneous adverse reactions:

Severe cutaneous adverse reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome and drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in some patients on cefixime. When severe cutaneous adverse reactions occur, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Clostridium difficile associated disease (e.g. pseudomembranous colitis):

Diarrhea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with various, but especially broad spectrum antibiotics, may be symptomatic of Clostridium difficile-associated disease, the most severe form of which is pseudo-membranous colitis. The diagnosis of this rare but possibly fatal condition is confirmed by endoscopy and/or histology.

Screening of faeces for this pathogen and above all its cytotoxin, is the best way to diagnose Clostridium difficile associated disease.

If a diagnosis of pseudomembranous colitis is suspected, Kuracef should be stopped immediately and appropriate specific antibiotic therapy should be started without delay (e.g. oral vancomycin or metronidazole).

Clostridium difficile associated disease can be favoured by faecal stasis.

As with other cephalosporins, cefixime may cause acute renal failure including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Kuracef should be administered with caution in patients with markedly impaired renal function.

Anaphylactic reactions:

The prescription of cephalosporins necessitates preliminary enquiry with regard to allergic diathesis and particularly with regard to hypersensitivity to β-lactam antibiotics.

If a hypersensitivity reaction occurs, treatment must be stopped.

The use of cefotaxime is strictly contra-indicated in subjects with a previous history of immediate-type hypersensitivity to cephalosporins. In any doubt, it is essential that a physician be present during the first administration, to treat any possible anaphylactic reaction.

Since cross allergy exists between penicillins and cephalosporins in 5 to 10 % of cases, use of the latter should be undertaken with extreme caution in penicillin sensitive subjects; careful monitoring is mandatory for the first administration. Hypersensitivity reactions (anaphylaxis) occurring with these two antibiotic families may be serious or even fatal.

Hypersensitivity to penicillins:

Cefixime should be administered with caution to patients with a history of hypersensitivity to penicillins.

Haemolytic anaemia:

Drug-induced haemolytic anaemia, including severe cases with a fatal outcome, has been described for cephalosporins (as a class). The recurrence of haemolytic anaemia after readministration of cephalosporins in a patient with a history of cephalosporin (including cefixime) -associated haemolytic anaemia has also been reported.

Renal failure acute:

As with other cephalosporins, cefixime may cause acute renal failure including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Renal impairment:

Cefixime should be used with particular care in the presence of severely impaired renal function (see "Pharmacokinetic properties" section).

Pediatric use:

Safety of cefixime in premature or newborn infant has not been established.

Encephalopathy:

Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

PRECAUTIONS

In patients allergic to other beta-lactams, it is necessary to consider potential cross allergy.

Renal insufficiency:

The dosage should be modified based on creatinine clearance.

INTERACTIONS

Coumarin-type anticoagulants:

Cefixime should be administered with caution to patients receiving coumarin-type anticoagulants, e.g. warfarin potassium. Since cefixime may enhance effects of the anticoagulants, prolonged prothrombin time with or without bleeding may occur.

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Other forms of interaction:

- The administration of cefixime may result in false-positive results for glucose in the urine using Benedict's solution, Fehling's solution, or Clinitest. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (e.g. Tes-Tape) be used.
- A false-positive direct Coomb's test may occur during treatment with cefixime.

PREGNANCY

Safety of cefixime in pregnant woman has not been established. There are no well-controlled studies with Kuracef in pregnant women.

Therefore, Kuracef should be used in pregnant women or in women of childbearing potential only if the potential benefit justifies the potential risk to the fetus.

LACTATION

It is not known whether cefixime is excreted in human milk. There is insufficient information on the excretion of cefixime/metabolites in human milk.

A risk to the suckling child cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Kuracef therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Driving a vehicle or performing other hazardous tasks

In the case of adverse reactions such as **encephalopathy** (which may include convulsions, confusion, Impairment of consciousness, movement disorders), the patient should not operate machines or drive a Vehicle.

ADVERSE REACTIONS

Infections and infestations:

Frequency not known:

Pseudomembranous colitis (see WARNINGS), vaginitis

Blood and lymphatic system disorders:

Frequency not known:

Eosinophilia, agranulocytosis, leucopenia, neutropenia, granulocytopenia, haemolytic anaemia, thrombocytopenia, thrombocytosis.

Immune System disorders:

Frequency not known:

Anaphylactic reaction, angio-oedema, serum sickness-like reaction.

Nervous system disorders:

Frequency not known:

Dizziness, headache

Cases of convulsions have been reported with cephalosporins including cefixime

Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

Respiratory, thoracic and mediastinal disorders:

Frequency not known:

Dyspnoea.

Gastrointestinal disorders:

Frequency not known:

Abdominal pain, diarrhoea (see WARNINGS), dyspepsia, nausea, vomiting, flatulance.

Hepatobiliary disorders:

Frequency not known:

Jaundice, hepatitis

Skin and subcutaneous tissue disorders:

Frequency not known:

Drug rash with eosinophilia and systemic symptoms (DRESS), erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria, rash, pruritus

Renal and urinary disorders:

Frequency not known:

Acute renal failure with interstitial nephritis (see WARNINGS and PRECAUTIONS)

General disorders and administration site conditions:

Frequency not known:

Pyrexia

Investigations:

Frequency not known:

Aspartate aminotransferase increased, alanine aminotransferase increased, blood bilirubin increased, blood urea increased, blood creatinine increased

OVERDOSE

SIGNS AND SYMPTOMS

There is a risk of encephalopathy in cases of administration of beta-lactam antibiotics, including cefixime, particularly in case of overdose or renal impairment.

INTERFERENCES WITH LABORATORY AND DIAGNOSTIC TEST

Positive Coombs tests may occur during treatment with cephalosporins.

Urinary glucose testing with non-specific reducing agents, may yield a false-positive reaction in patients treated with cefixime. This phenomenon is not seen when a glucose-oxydase specific method is used.

PHARMACEUTICAL PARTICULARS

- Tablet should be stored below 25°C.
- Keep the medicines in a safe place, out of the reach of children.
- Away from the light.
- Do not use later than the date of expiry.

PACKAGE QUANTITIES

Kuracef 200mg Tablet: Carton of 3X4's Tablet in alu-alu blister.

Kuracef 400mg Tablet: Carton of 2X4's tablet in alu-alu blister.

Kuracef suspension: Bottles containing dry powder to reconstitute 30ml and 50 ml suspension.

Manufactured by:
Sanofi Bangladesh Limited
Station Road, Tongi, Gazipur. 000000

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