SK-cef®

Cephradine Monohydrate USP

Capsule / Powder for Suspension / Paediatric Drops / Injection

DESCRIPTION

SK-cef® is a preparation of Cephradine. It is a broad spectrum, bactericidal antibiotic, active against *gram-positive* and *gram-negative* bacteria. It has a high degree of stability to many beta-lactamases. It is also highly active against most strains of penicillinase-producing *staphylococci*. ***SK-cef***® has a low degree of protein binding and large volume of distribution. Therefore, tissue levels are generally found to be high.

INDICATIONS

SK-cef® is indicated for the infections due to sensitive *gram-positive* and *gram-negative* bacteria. These infections include:

- **Upper respiratory tract infections:** Pharyngitis, sinusitis, otitis media, tonsillitis, laryngo-tracheo-bronchitis.
- **Lower respiratory tract infections:** Acute and chronic bronchitis, lobar and bronchopneumonia.
- **Urinary tract infections:** Cystitis, urethritis, pyelonephritis and prostatitis.
- **Skin and soft tissue infections:** Abscess, cellulitis, furunculosis and impetigo.

SK-cef® is indicated for the prophylaxis of surgery. It has been shown to be effective in reducing the incidence of post-operative infection in patients undergoing surgical procedures associated with a high risk of infection.

DOSAGE AND ADMINISTRATION

Adult:

250 to 500 mg every 6 hours or 0.5 to 1 g every 12 hours. It may be given up to 1 g 6 hourly according to the severity of infections.

For respiratory tract infections (other than lobar pneumonia) and skin infections: The usual dose is 250 mg or 500 mg 6 hourly or 500 mg or 1 g 12 hourly.

For lobar pneumonia: The usual dose is 500 mg 6 hourly or 1 g 12 hourly.

For urinary tract infections including prostatitis: The usual dose is 500 mg 6 hourly or 1 g 12 hourly.

For uncomplicated urinary tract infections: The usual dose is 500 mg 12 hourly.

Injections: The usual dose is 0.5 to 1 g 6 hourly should be given by intramuscular or intravenous route, over 3 to 5 minutes, may be increased up to 8 g daily in severe infections.

Surgical prophylaxis: Recommended dose is 1 to 2 g by intramuscular or intravenous injection over 3 to 5 minutes at induction. Subsequent parenteral or oral doses are given as appropriate.

Children:

25 to 50 mg/kg/day in equal divided doses every 6 or 12 hours. For otitis media, the usual dose vary from 75 to 100 mg/kg/day in equal divided doses every 6 or 12 hours, but should not exceed 4 g per day.

Injections: 50 to 100 mg/kg/day in 4 equally divided doses. The usual total dose may be increased up to 200 to 300 mg /kg/day.

CONTRAINDICATION

Patients with known hypersensitivity to the cephalosporin; porphyria.

PRECAUTIONS

Penicillin sensitivity; renal impairment; pregnancy and breast-feeding (but appropriate to use); false positive urinary glucose (if tested for reducing substances) and false positive Coombs' test.

USE IN PREGNANCY AND LACTATION

Pregnancy: The safety of Cephradine in pregnancy has not been established. The drug should be used during pregnancy only when clearly indicated.

Lactating mothers: Cephradine is excreted in breast milk and should be used with caution in lactating mothers.

DIRECTION FOR USE

SK-cef® **500 Injection:**

Intramuscular (IM): Add 2 ml of Water for Injection to 500 mg vial and shake.

Intravenous (IV): Add 5 ml of Water for Injection to 500 mg vial and shake. The solution should be slowly injected directly into a vein over 3 to 5 minutes period.

***SK-cef*® 1 g Injection :**
Intramuscular (IM): Add 4 ml of Water for Injection to 1 g vial and shake.
Intravenous (IV): Add 10 ml of Water for Injection to 1 g vial and shake. The solution should be slowly injected directly into a vein over 3 to 5 minutes period.

SIDE-EFFECTS

Side-effects include diarrhoea and rarely antibiotic-associated colitis (CSM has warned both more likely with higher doses), nausea , vomiting, abdominal discomfort, headache. Allergic reactions including rashes, pruritus, urticaria, serum sickness-like reactions with rashes, fever, arthralgia and anaphylaxis. Erythema multiforme, toxic epidermal necrolysis may also be reported. Disturbances in liver enzymes, transient hepatitis and cholestatic jaundice may occur. Other side-effects may be reported include eosinophilia and blood disorders (including thrombocytopenia, leucopenia, agranulocytosis, aplastic anaemia and haemolytic anaemia). Reversible interstitial nephritis, hyperactivity, nervousness, sleep disturbances, hallucinations, confusion, hypertonia and dizziness may occur.

DRUG INTERACTIONS

There is evidence of partial cross allergenicity between the penicillins and cephalosporins. There have been instances of patients who have had reactions to both drug classes (including anaphylaxis). Therefore, Cephradine should be used with caution in those patients with known hypersensitivity to penicillins. Loop diuretics may increase nephrotoxicity of cephalosporins as well as probenecid increase plasma concentration of cephalosporins.

PHARMACEUTICAL PRECAUTIONS

Store in a cool (below 30°C), dry place and away from light. Keep out of the reach of children. The reconstituted Cephradine injection solution should be used within 2 hours of preparation if kept at room temperature or within 12 hours if kept in a refrigerator at 2° - 8°C.

PACKAGING

***SK-cef*® 250 Capsule**	:	Box containing 8 strips of 6 capsules each. Each capsule contains Cephradine Monohydrate USP equivalent to Cephradine 250 mg.
***SK-cef*® 500 Capsule**	:	Box containing 5 strips of 6 capsules each. Each capsule contains Cephradine Monohydrate USP equivalent to Cephradine 500 mg.
***SK-cef*® Powder for Suspension**	:	Bottle containing powder for the preparation of 100 ml suspension. After reconstitution each 5 ml contains Cephradine Monohydrate USP equivalent to Cephradine 125 mg.
***SK-cef*® DS Powder for Suspension**	:	Bottle containing powder for the preparation of 60 ml /100 ml suspension. After reconstitution each 5 ml contains Cephradine Monohydrate USP equivalent to Cephradine 250 mg.
***SK-cef*® Powder for Paediatric Drops**	:	Bottle containing powder for the preparation of 15 ml suspension. After reconstitution each 1.25 ml contains Cephradine Monohydrate USP equivalent to Cephradine 125 mg.
***SK-cef*® 500 IM/ IV Injection**	:	Box containing one vial of Cephradine USP 500 mg and one ampoule of 5 ml Water for Injection USP.
***SK-cef*® 1 g IM/ IV Injection**	:	Box containing one vial of Cephradine USP 1 g and one ampoule of 10 ml Water for Injection USP.

SK+F

Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH
® REGD.TRADEMARK

PM01230 V02