

eskacef® PRESCRIBING INFORMATION

Capsules, Suspension

Composition:

Capsules

eskacef 250: white capsules with opaque scarlet red cap.

eskacef 500: opaque orange capsule.

Each capsule contains:

Active ingredient: Cephadrine 250mg or 500mg.

Excipients: Magnesium stearate, talc, and lactose.

Suspension

Each teaspoonful (5mL) of the suspension contains:

Active ingredient: Cephadrine 125mg or 250mg.

Excipients: Sodium citrate, citric acid, guar gum, methylcellulose, FD&C yellow No. 6, blood orange flavour, orange banana flavour, and sucrose.

Uses:

Cephadrine is a broad-spectrum bactericidal antibiotic indicated in the treatment of a wide range of bacterial infections.

It is indicated in: Upper respiratory tract infections, lower respiratory tract infections, urinary tract infections, gastrointestinal tract infections, and skin and soft-tissue infections.

Cephadrine may be used for the prevention of bacteraemia in patients undergoing surgical procedures associated with high risk of infection. Cephadrine should be administered immediately prior to surgery to help ensure adequate concentrations during the time contamination is likely to occur, and should be continued during the postoperative period to reduce the incidence of postoperative infection.

Cephadrine is bactericidal against both Gram-positive and Gram-negative bacteria and most strains of penicillinase-producing *Staphylococci*.

Gram-positive: *Staphylococci* (both penicillin-sensitive and resistant strains), *Streptococcus pyogenes* (beta-haemolytic), group D *Streptococcus* (enterococci), and *Streptococcus pneumoniae*.

Gram-negative: *Escherichia coli*, *Proteus mirabilis*, *Haemophilus influenzae*, *Klebsiella* spp., *Shigella* spp., *Salmonella* spp. (including *Salmonella typhi*), and *Neisseria* spp.

Enterococci may be susceptible to the high levels of cephadrine achieved in the urine.

Dosage and Administration:

Cephadrine may be given without regard to meals. Treatment should be continued for a minimum of 48-72 hours after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. The usual daily dose is as the following:

Adults:

- Respiratory tract infections: 1g-2g in divided doses (either two or four times daily).
- Urinary tract infections: 2g in divided doses (either two or four times daily).
- Complications of the urinary tract infections such as prostatitis and epididymitis may require prolonged intensive therapy.
- Gastrointestinal tract infections: 1.5g-2g in divided doses (either three or four times daily).
- Skin and soft-tissue infections: 1g-2g in divided doses (either two or four times daily).

Children:

25-50mg/kg/day to be administered two or four times a day in equally divided doses.

For otitis media daily doses from 75-100mg/kg every 6 to 12 hours are recommended, to a maximum daily dose of 4g.

Elderly:

There are no specific dosage recommendations or precautions for use in the elderly except, as with other drugs, to monitor those patients with impaired hepatic or renal function.

Severe and chronic infections in all patients, regardless of age and weight, may require up to 1g four times a day.

As prophylaxis against rheumatic fever or glomerulonephritis, infections caused by hemolytic strains of *Streptococci* should always be treated for a minimum of 10 days.

If you miss a dose:

- Take the missed dose as soon as you remember.
- If it is almost time for your next dose, wait until then to take your medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications, Warnings etc.:

Contraindications:

Cephadrine is contraindicated in patients with known hypersensitivity to the cephalosporin group of antibiotics.

Cautions:

Cephadrine should be administered with caution in patients with known hypersensitivity to penicillins. Rarely, cephadrine may induce hypersensitivity reactions, usually in patients who have a history of allergy. Caution should also be exercised when treating patients with renal impairment. The patient should be observed clinically and laboratory tests performed regularly prior to and during treatment with cephadrine. After treatment with cephadrine, a false positive test for glucose in the urine may occur with Benedict's solution, Fehling's solution or reagent tablets such as Clinitest. Enzyme-based tests such as Clinistix are not affected by cephadrine.

Prolonged use may result in the overgrowth of nonsusceptible organisms.

Pregnancy and lactation: Cephadrine is not known to be harmful during pregnancy and lactation, although it diffuses across the placenta and small quantities are found in the milk of nursing mothers.

Adverse Reactions:

Adverse reactions are rare but include:

Gastrointestinal: nausea and vomiting, diarrhoea, glossitis, and heartburn. Pseudomembranous colitis has been reported rarely.

Hypersensitivity: urticaria, skin rashes, tightness in the chest, and joint pains.

Hematological: positive direct Coomb's test and mild transient eosinophilia, leucopenia and neutropenia.

Clinical Chemistry: isolated incidences of elevated liver enzymes have been observed, however, no consistent pattern suggestive of hepatocellular damage has been seen. Isolated incidences of mild elevations of BUN have also been reported.

Overdosage:

Since there is no specific antidote, treatment of cephadrine overdose should be symptomatic.

Drug Interactions:

Probenecid may reduce the excretion of cephadrine, thereby increasing its plasma concentrations upon concurrent use.

Presentations:

eskacef capsules 250mg or 500mg: Packs of 12 or 20 capsules.
Hospital packs of 500 or 1000 capsules.

eskacef suspension 125mg/5mL or 250mg/5mL: Bottles of 60 or 100mL.

- * Store at room temperature not exceeding 25°C, in a dry place. Protect the capsules from light. After reconstitution of the suspension, unused portion stored at room temperature should be discarded after 7 days. When stored in refrigerator, discard unused portion after 14 days.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

Any information ? Call Our Toll Free No. (971) 800-4994



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