Rocef® (Cephradine) is a cephalosporin antibiotic with broad spectrum bactericidal activity against both gram-positive and gram-negative bacteria. It is also highly active against most strains of penicillinase producing staphylococci. The organisms sensitive to cephradine are: Gram-positive: Staphylococci (both penicillin sensitive and resistant strains), Streptococci including both Streptococcus pyogenes (beta haemolytic) and group D Streptococci (enterococci) and Streptococcus pneumoniae.

Gram negative: E. coli, Klebsiella, P. mirabilis, Hemophilus influenzae, Shigella spp. (including Salmonella typhi) and Neisseria spp. Enterococci (S. faecalis) and many strains of E. coli and Staphylococcus aureus are also susceptible. Rocef® (Cephradine) is rapidly absorbed from the gastrointestinal tract. Absorption is delayed by presence of food although the total amount absorbed is not appreciably altered.

Composition:
Rocef® 250 capsule: Each capsule contains Cephradine BP 250 mg.
Rocef® 500 capsule: Each capsule contains Cephradine BP 500 mg.
Rocef® Dry Syrup: After reconstitution each 5 ml syrup contains Cephradine BP 125 mg.
Rocef® Forte Dry Syrup: After reconstitution each 5 ml syrup contains Cephradine BP 250 mg

Indication:
Rocef® (Cephradine) is used in the treatment of infections caused by sensitive organisms.

Upper respiratory tract infections: Pharyngitis, sinusitis, otitis media, tonsillitis, laryngotracheo-bronchitis.

Lower respiratory tract infections: Acute and chronic bronchitis, lobar and bronchopneumonia.

Urinary tract infections: Cystitis, urethritis, pyelonephritis.

Skin and soft tissue infections: Abscesses, cellulitis, furunculosis, impetigo.

Gastrointestinal tract infections: Bacillary dysentery, enteritis, peritonitis.

Bone & joint infection.

Surgical prophylaxis: It is also used in perioperative prophylactic administration (pre-operatively, intra-operatively & post-operatively). In cesarean section, intra-operative (after clamping the umbilical cord) and post-operative use may reduce the incidence of certain post-operative infection.

Dosage and Administration:
The dosage may be given without regard to meals.

Adult: Oral: The usual dose is 1-2 gm daily in 2 to 4 divided doses. In severe and prolonged infection, the dose can be increased up to 4 gm daily which should be taken in equally divided doses. Special dose in the following infections:

Skin and skin structures and respiratory tract infection: Usual dose is 250 mg every 6 hours or 500 mg every 12 hours.

Lobar pneumonia: 500 mg every 6 hours or 1 gm every 12 hours.

Urinary tract infection: Usual dose is 500 mg every 12 hours.

Gastro intestinal tract infection: 500 mg three to four times daily.

Children: Oral: The usual total dose is 25 to 50 mg/kg/day given in 2 to 4 equally divided doses.

Perioperative prophylaxis: Recommended dose is 1-2 gm by intramuscular or intravenous route; subsequent parenteral or oral doses are given as appropriate. Therapy should be continued for a minimum of 48-72 hrs. after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

Dosage in renal impairment:
In patients with impaired renal function, doses and frequency of administration of cephradine must be modified according to the degree of impairment, severity of infection, susceptibility of the causative organism and serum concentration of the drug. For adults, a loading dose of 750 mg should be given subsequently followed by 500 mg with the mentioned time interval.

<table>
<thead>
<tr>
<th>Creatinine clearance (ml/min)</th>
<th>Time interval (hrs)</th>
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</thead>
<tbody>
<tr>
<td>&gt; 20</td>
<td>6-12</td>
</tr>
<tr>
<td>15-19</td>
<td>12-24</td>
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<tr>
<td>10-14</td>
<td>24-40</td>
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<tr>
<td>5-9</td>
<td>40-50</td>
</tr>
<tr>
<td>&lt;5</td>
<td>50-70</td>
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</tbody>
</table>

For children, dosage schedule may need to be adjusted.

Reconstitution & Administration:
Rocef® Dry Syrup: For the syrup, shake the bottle well before adding water. Then add 65 ml of boiled and cool water (with the help of the provided cup) to the bottle. Then continue shaking the bottle gently until the powder is dissolved properly. Shake the bottle well before each use.

Rocef® Forte Dry Syrup: For the syrup, shake the bottle well before adding water. Then add 65 ml of boiled and cool water (with the help of the provided cup) to the bottle. Then continue shaking the bottle gently until the powder is dissolved properly. Shake the bottle well before each use.

Side Effects:
Side effects include nausea, vomiting, diarrhoea and abdominal discomfort. Allergic reactions including skin rashes, urticaria, eosinophilia, angioedema and anaphylaxis may occur and elevation of hepatic enzyme values have been noted. Neutropenia has been reported. Super-infection with resistant microorganisms, particularly candida, may follow the treatment. There is also a possibility of development of pseudomembranous colitis. Thrombophlebitis has been reported following intravenous administrations.

Precaution:
Cephradine should be used with caution in those patients who are known hypersensitive to penicillins.

Use in Pregnancy and Lactation:
Although there have been no reports of adverse effect on the fetus, safety of use during pregnancy has not been definitely established. The drug should be used during pregnancy only when clearly indicated. Cephalosporins are distributed into breast milk and the drug should be used with caution in nursing women.

Contraindication:
It should not be used in patients hypersensitive to any cephalosporin antibiotic.

Pharmaceutical Precaution:
Cephradine capsule and dry powder for syrup should be kept in a cool and dry place, protected from light. The reconstituted syrup should be used within 7 days of preparation, if kept at room temperature or within 14 days if kept in a refrigerator. The cephradine solution should be protected from bright or direct sunlight.

How supplied:
Rocef® 250 Capsule: Box containing 5 x 6 capsules in Alu-Alu strip pack
Rocef® 500 Capsule: Box containing 4 x 6 capsules in Alu-Alu strip pack
Rocef® Dry Syrup: Bottle containing Rocef® dry powder to reconstitute 100 ml syrup.
Rocef® Forte Dry Syrup: Bottle containing Rocef® dry powder to reconstitute 100 ml syrup.

Storage:
Store in a cool and dry place below 30°C. Protect from light and moisture.

Medicine: Keep out of reach of children