Dar Al Dawa

CLORACEF® MR Cefaclor

DESCRIPTION :

Cloracef® MR (cefaclor modified release tablets) is a semisynthetic cephalosporin antibiotic for oral administration, and it is used for the treatment of broad range of gram-positive and gram-negative bacteria.

PHARMACOLOGY:

The extent of absorption and the maximum plasma concentration of cefaclor MR are greater when the extended release tablet is taken with food. The plasma half-life in healthy subjects is independent of dosage form and averages approximately one hour. When cefaclor MR is taken with food, the AUC is 10% lower while the Cmax is 12% lower and occurs one hour later compared to cefaclor capsules. In contrast, when cefaclor MR is taken without food, the AUC is 23% lower while the Cmax is 67% lower and occurs 0.6 hours later, compared to an equivalent milligram dose of cefaclor capsules as a reference. Therefore, cefaclor MR should be taken with food.

INDICATIONS :

Cloracef® MR is indicated for the treatment of patients with the following infections.

- Acute bacterial exacerbations of chronic bronchitis due to H. influanzae (Including ß-lactamase-producing strains), M. catarrhalis (including ß-lactamase - producing strains) or S. pneumoniae.
- Secondary bacterial infections of acute bronchitis due to H. influanzae (including ß-lactamase-producing strains), M. catarrhalis (including ß-lactamase - producing strains), or S. pneumoniae.
- Pharyngitis and tonsillitis due to S. pyogenes.
- Skin and skin structure infections due to S. aureus (methicillin- susceptible).
- Lower UTI.

CONTRAINDICATIONS :

Cloracef® MR is contraindicated in patients with known hypersensitivity to cefaclor or other cephalosporins.

SIDE EFFECTS :

Side effects occurring with cefaclor modified release with an incidence of less than 1% but greater than 0.1% included the following:

Central nervous system: somnolence, nervousness , dizziness, insomnia.

Dermatologic: Urticaria, rash.

Gastrointestinal: nausea, vomiting, diarrhea, anorexia.

PRECAUTIONS:

- Superinfection should always be considered a possibility in patients being treated with a broad-spectrum antimicrobial. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.
- If an allergic reaction to cefaclor occurs, discontinue the drug. Caution should be exercised because cross - sensitivity among beta - lactam antibiotics has been documented.
- Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefaclor and may range from mild to severe, therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
- Pregnancy: There are no adequate and well - controlled studies in pregnant women. cefaclor should be used during pregnancy only if clearly needed.
- Nursing mothers: Caution should be exercised when cefaclor is administered to nursing women, since small amounts of cefaclor have been detected in human milk.

DRUG INTERACTIONS:

Antacids: The extent of absorption of cefaclor is diminished if magnesium or aluminum hydroxide containing antacids are taken within 1 hour of administration. Probenecid: probenecid decreases renal tubular secretion of cefaclor, resulting in increased and prolonged cefaclor serum concentration. Warfarin: There have been rare reports of increased prothrombin time with or without clinical bleeding in patients receiving cefaclor and warfarin concomitantly.Laboratory tests: Administration of **Cloracef® MR** may result in a false- positive reaction for glucose in the urine.

DOSAGE :

- For pharyngitis, tonsillitis skin and skin structure infections, the recommended dosage is 375 mg BID.
- For lower UTI's, the recommended dosage is 375 mg BID or 500 mg once daily.
- For bronchitis, the recommended dosage is 375 mg - 500 mg BID.
- For pneumonia and sinusitis, the recommended dosage is 750 mg BID.

NOTES:

- The absorption of **Cloracef® MR** is enhanced with food.
- The modified release tablets should not be cut, crushed or chewed.
- Elderly patients with normal renal function do not require dosage adjustments.

OVERDOSAGE:

Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases is more effective than emesis or lavage.

PRESENTATIONS:

Cloracef® MR 375: pack of 10 Film Coated Tablets, each tablet contains 375 mg Cefaclor (as cefaclor monohydrate).

Cloracef® MR 500: pack of 10 Film Coated Tablets, each tablet contains 500 mg of Cefaclor (as cefaclor monohydrate).

Cloracef® MR 750: pack of 10 Film Coated Tablets, each tablet contains 750 mg of Cefaclor (as cefaclor monohydrate).

STORAGE CONDITIONS:

Store in a dry place up to 30˚C.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, it's 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 medicament out of reach of children

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Manufactured by Dar Al Dawa , Na'ur - Jordan