CEFALEXIN

DIACEF

℞

250 mg Capsule and 500 mg Capsule

ANTIBACTERIAL (CEPHALOSPORIN)

PRODUCT DESCRIPTION:
Cefalexin (DIACEF) is a white to off-white crystalline powder contained in a rich yellow opaque/rich yellow opaque capsule size #1 (250 mg) and yellow opaque/dark gray capsule size #0 (500 mg)

FORMULATION:
Each capsule contains:
Cefalexin (As Monohydrate), USP . . . . . 250 mg/500 mg

PHARMACODYNAMICS:
Cefalexin exerts its bactericidal activity by interfering with the synthesis of the bacterial cell wall. It binds to specific penicillin-binding proteins responsible for the synthesis of peptidoglycan, a heteropolymeric structure that gives the cell wall its mechanical stability. The final stage of peptidoglycan synthesis involves completion of the cross-linking of the terminal glycine residue of the pentaglycine bridge to the fourth residue of the pentapeptide. The transpeptidase that catalyzes this step is inhibited by cephalosporins. As a result, the bacterial cell wall is weakened, the cell swells and then ruptures.

PHARMACOKINETICS:
Cefalexin is available for oral administration and it has the same antibacterial spectrum as the other first generation cephalosporins. However, it is somewhat less active against penicillinase-producing staphylococci. Oral therapy with Cefalexin results in peak concentrations in plasma of 10 mg/mL after a dose of 0.5 g: this is adequate for the inhibition of many gram-positive and gram-negative pathogens that are sensitive to cephalothin, a drug that is not well absorbed orally and is available only for parenteral administration. Cefalexin is not metabolized and more than 90% is excreted in the urine.

INDICATION:
For the treatment of infections of the respiratory, gastrointestinal and urinary tract. Indicated also for otic, bone, skin and soft tissue, including penicillinase producing staphylococcus aureus infection.

DOSAGE AND ADMINISTRATION:
The usual dose for adults is 1 - 2 g daily given in divided doses at 6, 8, or 12 - hourly intervals. Or as prescribed by the physician.

CONTRAINDICATION:
Hypersensitivity to Cephalosporins, extreme caution should be exercised in penicillin allergic patients.

PRECAUTION AND WARNING:
Use with caution in patients receiving aminoglycoside antibiotics or potent diuretics such as furosemide. In patients with impaired renal function, decrease in doses and/or frequency of administration of Cefalexin may be required and should be based on the degree of renal impairment, severity of infection, susceptibility of the causative organism, and serum concentrations of Cefalexin.

PREGNANCY AND LACTATION:
Cefalexin is categorized as Pregnancy Category B where potential benefits should outweigh the potential risks. Caution should be exercised when the drug is given to a breastfeeding woman.

DRUG INTERACTION:
The renal excretion of cefalexin and many other cephalosporins is delayed by probenecid.

ADVERSE DRUG REACTION:
The most common adverse effects of cefalexin and other oral cephalosporins are generally gastrointestinal disturbances and hypersensitivity reactions. Pseudomembranous colitis has been reported.

OVERDOSE AND TREATMENT:
Overdose symptoms with Cefalexin may include nausea, vomiting, epigastric distress, stomach pain, diarrhea and blood in the urine (hematuria). Administration of activated charcoal may decrease the absorption of drugs from the gastrointestinal tract, which in many cases, is more effective than emesis or lavage.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C and protect from direct sunlight

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
Cefalexin (DIACEF) 100 mg/mL Powder for Suspension - Amber Bottle x 10 mL
Cefalexin (DIACEF) 125 mg/5 mL Powder for Suspension - Amber Bottle x 60 mL
Cefalexin (DIACEF) 250 mg/5 mL Powder for Suspension - Amber Bottle x 60 mL
Cefalexin (DIACEF) 250 mg & 500 mg Capsule - Blister pack by 10's, box of 100's

REGISTRATION NUMBER AND DATE OF RENEWAL AUTHORIZATION:
Cefalexin (DIACEF) 250 mg Capsule - DRP-151 - April 18, 2023
Cefalexin (DIACEF) 500 mg Capsule - DRP-150 - March 22, 2023

PACKAGE INSERT DATE OF REVISION:
August 14, 2023

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph."
Seek medical attention immediately at the first sign of any adverse drug reaction.

Manufactured by the
Marketing Authorization Holder:
DIAMOND LABORATORIES, INC.
8 Feria Rd., Commonwealth Ave.,
Diliman, Quezon City

Distributed by:
RILEM PHARMA CORP.
2711 P. Zamora Street,
Pasay City

GRAPHIC ARTIST: Mar	DATE SUBMITTED: 08.19.2023_03	APPROVED DATE:
JOB DESCRIPTION: DIACEF 250 mg - 500 mg Insert - Update 2023	CLIENT SIGNATURE:	