Rx

Cefalexin
Medilexin®

500 mg Capsule
100 mg/mL Powder for Suspension (Oral Drops)
250 mg/5 mL Powder for Suspension
ANTIBACTERIAL
(CEPHALOSPORIN)

FORMULATION
Capsule
Each capsule contains:
CEFALEXIN (as monohydrate), USP .... 500 mg
Powder for Suspension (Oral Drops)
Each mL contains:
CEFALEXIN (as monohydrate), USP .... 100 mg
Suspension
Each 5 mL contains:
CEFALEXIN (as monohydrate), USP .... 250 mg

PRODUCT DESCRIPTION
Cefalexin Capsules: White to off-white crystalline compacted powder with Dark gray cap and yellow body. It complies with the USP specifications for Cefalexin capsules.
Cefalexin (Powder for Suspension/Oral Drops for Infants): White to off-white powder with Sweet Strawberry flavored pink suspension upon reconstitution. It complies with the USP specifications for Cefalexin Powder for Suspension (Oral Drops)
Cefalexin (Powder for Suspension): White to off-white powder with Sweet Strawberry flavored pink suspension upon reconstitution. It complies with the USP specifications for Cefalexin Powder for Suspension

PHARMACODYNAMICS
It is active against the following pathogens:
Gram Positive: *Staphylococci* (coagulase positive as well as penicillinase-producing strains), *Streptococci, pneumococci, Corneybacterium diptheriae, Bacillus anthracis, Clostridia, Listeria monocytogenes, Bacillus subtilis* and *Bacteriodes melaninogenicus*.
Gram Negative: *Escherichia coli, Salmonellae, Shigellae, Neisseria, Proteus mirabilis, Haemophilus influenzae (some strains), Brucellae, Klebsiella species, Treponema pallidum and actinomycetes.*

PHARMACOKINETICS
Cefalexin is almost completely absorbed from the gastrointestinal tract and produces a peak plasma concentration of about 18 micrograms/mL 1 hour after a 500-mg oral dose. If cefalexin is taken with food, absorption may be delayed, but the total amount absorbed is not appreciably altered. Up to 15% of a dose is bound to plasma proteins. The plasma half-life is about 1 hour; it increases with reduced renal function. Cefalexin is widely distributed in the body but does not enter the CSF in significant quantities. It crosses the placenta and small quantities are found in breast milk. Cefalexin is not metabolised. About 80% or more of a dose is excreted unchanged in the urine in the first 6 hours by glomerular filtration and tubular secretion; urinary concentrations greater than 1 mg/mL have been achieved after a dose of 500 mg. Probenecid delays urinary excretion. Therapeutically effective concentrations may be found in the bile and some may be excreted by this route. Cefalexin is removed by haemodialysis and peritoneal dialysis.

INDICATIONS
For the treatment of infection of the respiratory and urinary tracts, otitis media, skin and soft tissue including penicillinase-producing staphylococcus aureus infection.

DOSAGE AND MODE OF ADMINISTRATION
For Cefalexin 500 mg Capsule
1 to 2 grams daily given in divided doses at 6, 8, or 12 hourly intervals.
Or as prescribed by the physician
For Cefalexin 250mg/5mL Powder for Suspension
Children may be given 25 mg to 100 mg per kg body weight daily in divided doses to a maximum of 4 g daily
Or as prescribed by the physician
For Cefalexin 100 mg/mL Powder for Suspension (Oral Drops)
Children may be given 25 mg to 100 mg per kg body-weight daily in divided doses to a maximum of 4 g daily.
Or as prescribed by the physician

DIRECTIONS FOR RECONSTITUTION
For 250mg/5mL Powder for Suspension
To make 60 mL suspension, add 43 mL of water and shake well until the powder are evenly suspended. Reconstituted suspension is stable for 7 days at temperatures not exceeding 30°C and 14 days when refrigerated (2°C - 8°C).
For 100 mg/mL Powder for Suspension (Oral Drops)
To make 10 mL suspension, add 7 mL water and shake well until the powder is evenly suspended. Reconstituted suspension is stable for 7 days at temperatures not exceeding 30°C and 14 days under refrigeration (2°C 8°C).

CONTRAINDICATION
Cefalexin is contraindicated in patients with known allergy to Cephalosporin group of antibiotics. Severe systemic infections, which require parenteral cephalosporin treatment.

PRECAUTIONS
Renal impairment: Cefalexin should be administered with caution in presence of markedly impaired renal function as it is excreted mainly by the kidneys.
Superinfection: Prolonged use of cefalexin may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.
Ability to perform tasks that require judgement, motor or cognitive skills:
There are no effects on ability to drive or to operate machinery

PREGNANCY AND LACTATION
Fertility: There are no relevant data available
Pregnancy: There is no experimental or clinical evidence of teratogenic effects attributable to cefalexin, but Cefalexin should be administered with caution during pregnancy.
Lactation: Cefalexin is excreted in human milk in low concentrations and should be used with caution in nursing mothers.
The excretion of cefalexin in human breast milk increased up to 4 hours following a 500 mg dose. The drug reached a maximum level of 4 micrograms/mL, then decreased gradually and had disappeared 8 hours after administration.

INTERACTIONS
The renal excretion of cefalexin and many other cephalosporins is delayed by probenecid.
Hormonal contraceptives: There have been isolated reports of cefalexin decreasing the efficacy of oestrogen-containing oral contraceptives.

ADVERSE EFFECTS
The most common adverse effects of cefalexin and other oral cephalosporins are generally gastrointestinal disturbances and hypersensitivity reactions. *Pseudomembranous colitis* has been reported.
The most common are hypersensitivity reactions, including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness, and anaphylaxis. There may be a positive response to the Coombs' test although haemolytic anaemia rarely occurs. Neutropenia and thrombocytopenia have occasionally been reported. Agranulocytosis has been associated rarely with some cephalosporins. Bleeding complications related to hypoprothrombinaemia and/or platelet dysfunction have occurred especially with cephalosporins and cephamycins having an N-methylthiotetrazole side-chain, including

cefamandole	cefbuperazone	cefmenoxime
cefmetazole	cefonicid	cefoperazone
ceforanide	cefotetan	cefpiramide
latamoxef		

OVERDOSAGE AND TREATMENT
Overdosage
Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhea and haematuria.
Treatment
General management consist of close, clinical and laboratory monitoring of haematological, renal and hepatic functions and coagulation status until the patient is stable. Serum levels of cephalexin can be reduced by haemodialysis or by peritoneal dialysis.

STORAGE CONDITON
Store at temperatures not exceeding 30°C.

AVAILABILITY
Blister Foil x 10's (Box of 100's)
Amber Glass Bottle x 10 mL w/ dropper (Box of 1's) & 60 mL Amber Bottle with Secondary Box (Box of 1's)

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

ADR REPORTING STATEMENT
"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.

REGISTRATION NUMBER
DR-XY32326
DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION
September 26, 2006
DATE OF REVISION
October 2021

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For
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Received: 5/30/2022
Sent to JMT: 5/31/2022

GRAPHIC ARTIST: **JOSEPH A. GALLARDO**	DATE SUBMITTED: 05/30/2022	APPROVED DATE:
JOB DESCRIPTION: MEDILEXIN 500mg BACKPANEL	CLIENT SIGNATURE:	