



CEFALEXIN

LONAREL®

100 mg/mL Powder for Suspension
Oral Drops
ANTIBACTERIAL
(Cephalosporin)

FORMULATION

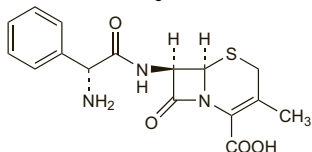
Each mL of reconstituted suspension contains:
CEFALEXIN monohydrate equivalent to CEFALEXIN USP 100 mg

PRODUCT DESCRIPTION

White to off-white powder. Sweet strawberry flavored pink suspension upon reconstitution.

DESCRIPTION

Cefalexin is a semisynthetic cephalosporin antibacterial drug intended for oral administration. It is 7-(D- α -Amino- α -phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid monohydrate. Cefalexin has the molecular formula C₁₆H₁₇N₃O₄SH₂O and the molecular weight is 365.41. Cefalexin has the following structural formula:



Cefalexin is a white to off-white crystalline powder. Slightly soluble in water, practically soluble in water, practically insoluble in alcohol, in chloroform, and in ether.

INDICATIONS

For the treatment of urinary tract infections, infections of the respiratory tract, otitis media, skin and other infections due to sensitive organisms.

PHARMACODYNAMICS

It is active against the following pathogens:

Gram Positive: *Staphylococci* (coagulase positive as well as penicillinase-producing strains), *Streptococci*, *pneumococci*, *Corynebacterium diphtheriae*, *Bacillus anthracis*, *Clostridia*, *Listeria monocytogenes*, *Bacillus subtilis* and *Bacterioides 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.

DOSEAGE AND MODE OF ADMINISTRATION

INFANTS

1-2 years old: 1.25 mL-2.5 mL (125 mg-250 mg)
6-12 months old: 0.75 mL-1.5 mL (75 mg- 150 mg)
3-6 months old: 0.5 mL- 0.75 mL (50 mg - 75 mg)
0-3 months old: 0.25 mL- 0.5 mL (25 mg - 50 mg)

All doses to be taken every six (6) hours.
Or as prescribed by a physician.

DIRECTIONS FOR RECONSTITUTION

Shake the bottle to loosen the powder. To make a 10 mL reconstituted suspension, mix thoroughly the contents with 7.0 mL water and shake well until the powder is evenly suspended. The reconstituted suspension is stable for 7 days at temperatures not exceeding 30°C. and 14 days when refrigerated (2°C-8°C).
Shake well before use.

PRECAUTIONS

Cefalexin should be used with caution in allergic patients, especially when there is a history of Penicillin allergy. Reduced dosage is recommended in some patients with severe renal impairment.

CONTRAINDICATIONS

Contraindicated in patients with known allergy to Cephalosporin group of antibiotics.

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 in caution in nursing mothers.

ADVERSE EFFECTS

The most common adverse effects of Cefalexin are hypersensitivity reactions, especially skin rashes; anaphylaxis occasionally occurs and has sometimes been fatal. Gastrointestinal effects such as diarrhoea and nausea are the most common adverse effects after oral use of Cefalexin; a sore mouth or tongue or a black hairy tongue have occasionally been reported. 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.

INTERACTIONS

The renal excretion of cefalexin, and many other cephalosporins, is delayed by probenecid.

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 cephalosporins can be reduced by haemodialysis or by peritoneal dialysis.

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.

STORAGE CONDITION

Store at temperatures not exceeding 30°C.

AVAILABILITY

Amber Glass Bottle x 10 mL (net content) with Plastic Dropper (Box of 1's)

REGISTRATION NUMBER

DRP-130

DATE OF FIRST AUTHORIZATION/ RENEWAL

October 16, 2006

DATE OF REVISION

March 2022



170 mm

105 mm

Insert required size:
105 mm x 170 mm
Required folding:
2 folds crosswise
(facing the text)