ARTWORK & DETAILS CHECKLIST FOR APPROVAL

K.L.C.A. PRINTING PRESS
Tel: 8749-2529 ■ Cp: 0919 098-2419

DATE: **FEBRUARY 16, 2023**
CLIENT: **APPEX MD'S PHARMACEUTICAL INC.**
JOB TITLE: **LEMAFLEX 250mg PFS**
DESCRIPTION: **60 ML INSERT (FOR NOTIFICATION)**

COLORS

PROCESS COLORS:
N/A | N/A
N/A | BLACK

PANTONE COLORS:

SIZE/DIMENSION

LENGTH: **105 mm ± 0.5 mm**
HEIGHT: **170 mm ± 0.5 mm**
WIDTH: **N/A**

PREPARED BY:
MARIUS CRUZ
(KLCA GRAPHIC ARTIST)

****KLCA PRINTING PRESS WATERMARK LOGOS ARE NOT INCLUDED OR PART OF THE ARTWORK DESIGN****

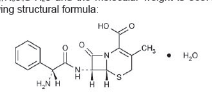
Rx CEFALEXIN
LEMAFLEX®
Antibacterial
(Cephalosporin)

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

FORMULATION:
Capsule Each capsule contains:
CEFALEXIN monohydrate equivalent to CEFALEXIN USP .... 500 mg
Suspension
Each 5 mL of reconstituted suspension contains:
CEFALEXIN monohydrate equivalent to CEFALEXIN USP ... 250 mg & 125 mg
Powder for Suspension (Oral Drops)
Each mL of reconstituted suspension contains:
CEFALEXIN monohydrate equivalent to CEFALEXIN USP .... 100 mg

PRODUCT DESCRIPTION
Cefalexin Capsules: Orange and yellow, hard gelatin capsule containing 500 mg of Cefalexin (as monohydrate). It complies with the USP specifications for Cefalexin capsules.
Cefalexin (Powder for Suspension): Prepared by adding water to the powder to give 60 mL flavored and colored suspension containing 250 mg and 125 mg of Cefalexin (as monohydrate) in each 5 mL. Both strengths comply with USP specifications for Cefalexin mixture.
Cefalexin (Powder for Suspension/Oral Drops for Infants): Prepared by adding water to the powder to give 10 mL strawberry-flavoured and colored suspension containing 100 mg of Cefalexin (as monohydrate) in each mL. It complies with USP specifications for Cefalexin mixture.

DESCRIPTION
Cefalexin is a semisynthetic cephalosporin antibacterial drug intended for oral administration. It is 7-(D-a-Amino-a-phenylacetamido)-3-methyl-3-cephem-4- carboxylic acid monohydrate. Cephalexin has the molecular formula $C_{16}H_{17}N_{3}0_{4}S{\bullet}H_{2}0$ and the molecular weight is 365.41. Cephalexin 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
Treatment of infections caused by Staphylococcus, Streptococcus, Diplococcus pneumoniae, Meningococcus and other susceptible organisms, in respiratory tract, urinary tract, gynecologic obstetric, skin, soft tissue and bone infections, gonorrhea, syphilis and dental procedures. Also active against strains of Staphylococcus aureus that are insensitive to Penicillin and against the majority ofAmpicillin resistant E. coli.

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.

DOSAGE AND MODE OF ADMINISTRATION
500 mg Capsule: Usual adult dose is 1 - 2 g (1,000 mg - 2,000 mg) daily given in divided doses at 6 - 8 -12 hourly intervals.

250 mg/5 mL Powder for Suspension

Adult	: Two (2) teaspoonful's (10 mL) three times a day.
Children:	
6 -12 years old	: One (1) teaspoonful (5 mL) three times a day.
1 - 5 years old	: One - half (1/2) teaspoon (2.5 mL) three times a day.
Below 1 year old	: One - half (1/2) teaspoon (2.5 mL) two times a day.

125 mg/5 mL Powder for Suspension

Children:	
6 -12 years old	: Two (2) teaspoonful's (10 mL) three times a day.
1 - 5 years old	: One (1) teaspoonful (5 mL) three times a day.
Below 1 year old	: One (1) teaspoonful (5 mL) two times a day.

100 mg/mL Powder for Suspension (Oral Drops)

Infants:	
1 - 2 years old	: 1.25 mL - 2.50 mL (125 mg - 250 mg)
6 -12 months old	: 0.75 mL -1.50 mL (75 mg -150 mg)
3 - 6 months old	: 0.50 mL - 0.75 mL (50 mg - 75 mg)
0 - 3 months old	: 0.25 mL - 0.50 mL (25 mg -50 mg)

All doses to be taken four (4) times a day.
Or as prescribed by a physician.

DIRECTIONS FOR RECONSTITUTION
For 250 mg/5 mL Powder for Suspension and 125 mg/5 mL Powder for Suspension.
Shake the bottle to loosen the powder. To make a 60 mL reconstituted suspension, mix thoroughly the contents with 43 mL water and shake well until the powder is evenly suspended.
For 100 mg/mL Powder for Suspension (Oral Drops)
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 not be given to patients who are hypersensitive to it or to other cephalosporins. Immunological studies have suggested that up to 20% of penicillin-sensitive patients may also be allergic to cephalosporins although clinical studies indicate a lower frequency and the true incidence is uncertain; great care should be taken if cefalotin is to be given to such patients. Care is also necessary in patients with a history of allergy. Cefalexin should be given with caution to patients with renal impairment; dosage reduction may be necessary. Renal and haematological status should be monitored especially during prolonged and high-dose therapy. Cefalexin and some other cephalosporins and cephamycins (ceforanide, cefotetan, cefoxitin, and cefpirome) may interfere with the Jaffe method of measuring creatinine concentrations and may produce falsely high values; this should be borne in mind when measuring renal function.

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

PREGNANCYAND 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 cephalexin 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
Blister of 10's, box of 100's
Amber bottles of 10 mL (with medicine dropper)
Amber Bottle x 60 mL (Box of 1 's).

DATE OF AUTHORIZATION/RENEWAL
March 29, 2023

DATE OF REVISION
OCTOBER 2022

Distributed by:
APPEX MD'S PHARMACEUTICAL INC.
1 Jade Street, Rockville 2 Subdivision,
San Bartolome, Quezon City, Metro Manila

Manufactured by:
JM TOLMANN LABORATORIES, INC.
#95 North Zuzuarregui St., Diliman, Q. C.

CHECKLIST FOR CLIENT

PLEASE CHECK THE FOLLOWING:

GRAPHICS & TEXT	☐ CONFORMS	☐ WITH CORRECTIONS
COLORS	☐ CONFORMS	☐ WITH CORRECTIONS
SIZE / DIMENSION	☐ CONFORMS	☐ WITH CORRECTIONS
☐ 1ST READING	☐ 2ND READING	☐ 3RD READING

CLIENT'S REMARKS

APPROVED AND CHECKED BY:

(Date & Signature Over Printed Name)

***NOTE:**
CLIENT has responsibility to proofread and review all artwork produced during the project. As a result, the client is fully responsible for any errors in spelling, typography, illustrative layout, photography or other errors discovered after printing or **reproduction or for** any work performed by third-parties selected by the **CLIENT.** Approved Artwork/Proof will be our basis for final printing.

"**IMPORTANT! Digital color output may not be 100% the same during actual printing. Digital printout may vary from the actual printing color."**