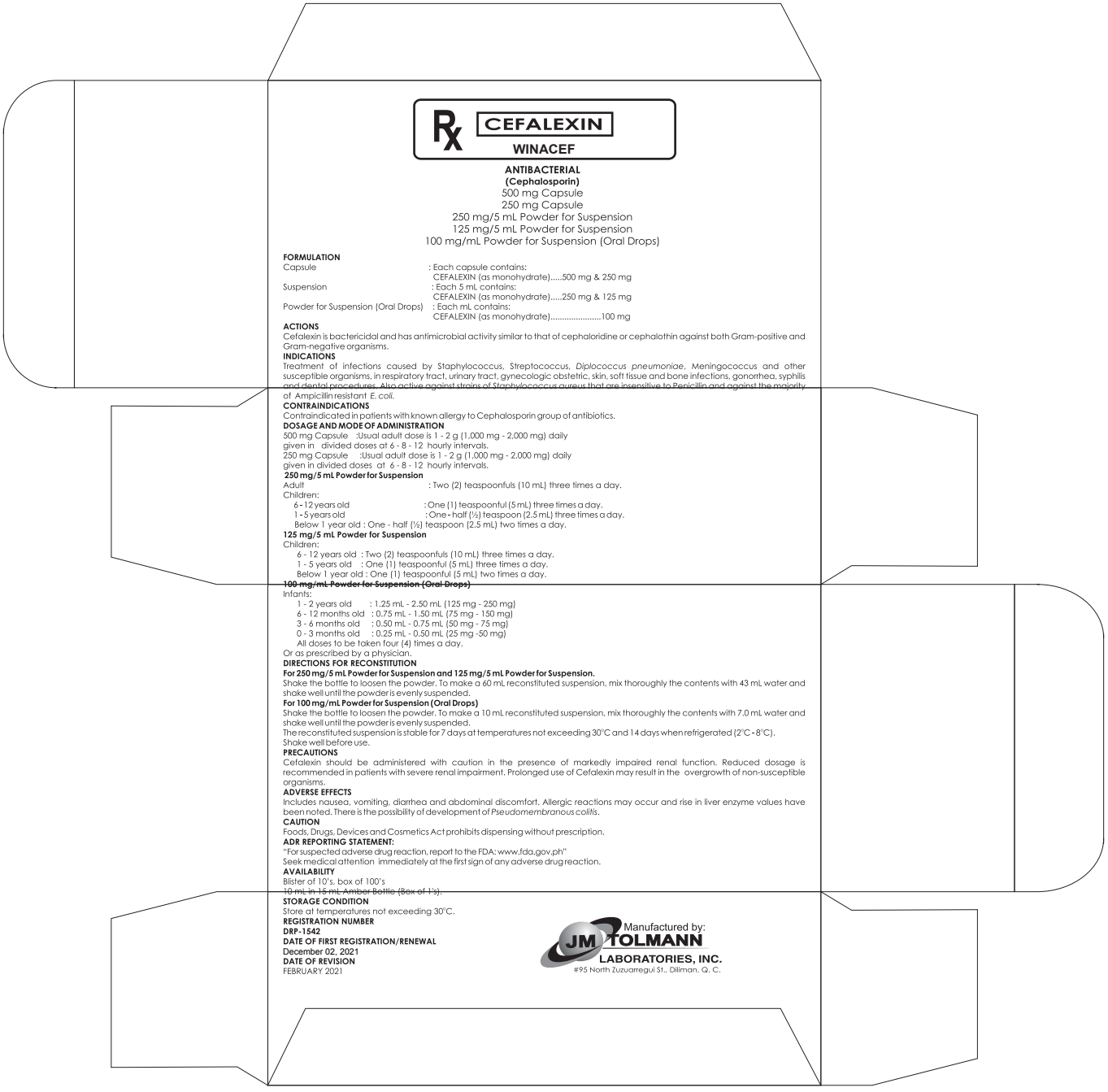
Product Information Printed on Inside panel of the box



Rx CEFALEXIN

WINACEF

ANTIBACTERIAL
(Cephalosporin)
500 mg Capsule
250 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 (as monohydrate).....500 mg & 250 mg
Suspension	: Each 5 mL contains: CEFALEXIN (as monohydrate).....250 mg & 125 mg
Powder for Suspension (Oral Drops)	: Each mL contains: CEFALEXIN (as monohydrate).....100 mg

ACTIONS
Cefalexin is bactericidal and has antimicrobial activity similar to that of cephaloridine or cephalothin against both Gram-positive and Gram-negative organisms.

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 of Ampicillin resistant *E. coli*.

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

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 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) teaspoonfuls (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 (½) teaspoon (2.5 mL) three times a day.
Below 1 year old : One - half (½) teaspoon (2.5 mL) two times a day.

125 mg/5 mL Powder for Suspension
Children:
6 - 12 years old : Two (2) teaspoonfuls (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 be administered with caution in the presence of markedly impaired renal function. Reduced dosage is recommended in patients with severe renal impairment. Prolonged use of Cefalexin may result in the overgrowth of non-susceptible organisms.

ADVERSE EFFECTS
Includes nausea, vomiting, diarrhea and abdominal discomfort. Allergic reactions may occur and rise in liver enzyme values have been noted. There is the possibility of development of *Pseudomembranous colitis*.

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.

AVAILABILITY
Blister of 10's, box of 100's
~~10 mL in 15 mL Amber Bottle (Box of 1's).~~

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

REGISTRATION NUMBER
DRP-1542
DATE OF FIRST REGISTRATION/RENEWAL
December 02, 2021
DATE OF REVISION
FEBRUARY 2021

Manufactured by:
JM TOLMANN LABORATORIES, INC.
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