Primera

CEFALEXIN
CEPHORAL

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

℞

FORMULATION:
Each capsule contains:
Cefalexin (as monohydrate), USP.....500 mg
Each 5 mL (1 teaspoonful) of reconstituted suspension contains:
Cefalexin (as monohydrate), USP.....250 mg
Each mL of reconstituted oral drops contains:
Cefalexin (as monohydrate), USP.....100 mg

PRODUCT DESCRIPTION:
Cefalexin (Cephoral) 500 mg white or almost-white, crystalline or semi-granular powder encapsulated in empty gelatin capsule size #0 with orange cap and yellow body.

Cefalexin (Cephoral) 250 mg/5 mL is an off-white to pinkish-white powder as dry product; pinkish suspension with strawberry/raspberry flavor and sweet fruit taste when reconstituted.

Cefalexin (Cephoral) 100 mg/mL is a white to off-white powder as dry product; white to off-white suspension with cherry/orange flavor and sweet fruit taste when reconstituted.

PHARMACODYNAMICS:
Cefalexin is a semi-synthetic broad spectrum first generation of cephalosporin which exerts its antibacterial activity by binding and inhibiting the action of bacterial cell wall synthesis enzyme. As a result of the interruption of peptidoglycan which lead to weaken bacterial cell and death.

PHARMACOKINETICS:
Cefalexin is acid stable and is almost completely absorbed from the gastrointestinal tract and produces peak plasma concentration 1 hour after administration. Serum concentrations are still detectable after 6 hours. Cefalexin diffuses readily into tissues which include bone, joints, and the pericardial as pleural cavities. Only 10%-15% of the dose is bound to plasma proteins. The drug crosses into the placenta and small quantity are found in breast milk. The serum half-life of cefalexin is 0.5 to 1.2 hours in adults with normal renal function. The serum half-life of cefalexin in neonates is reported to be about 5 hours and children 3 to 12 months of age is 2.5 hours. Cefalexin is not metabolized in the body. Elimination is mainly renal with 80% of the dose, excreted from the urine by both glomerular filtration and tubular secretion.

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

DOSAGE AND ADMINISTRATION:
500 mg Capsule
Cefalexin is given by oral administration.
Cefalexin capsule should be swallowed with water.
Adult: One capsule every 6 hours (maximum dose of 4 g/day) or as prescribed by the physician.

250 mg/5 mL Powder for Suspension
5-12 years: One teaspoonful (5 mL) every 6 hours
1-5 years: One half teaspoon (2.5 mL) every 6 hours or as prescribed by the physician.

100 mg/mL Powder for Suspension (Oral Drops)
Infants: 0.3 mL – 0.6 mL every 6 hours or as prescribed by the physician.

CONTRAINDICATIONS:
Cefalexin is contraindicated in patient with known hypersensitivity reaction to any excipients of the product, Penicillin and cephalosporin group of antibiotics.

WARNINGS AND PRECAUTIONS:
Should be used with caution in allergic patients, specially when there is a history of penicillin allergy. Reduced dosage is recommended in patients with severe renal impairment.

PREGNANCY AND LACTATION:
Pregnancy Category B:
There are no adequate and well-controlled studies in pregnant women. Cefalexin should be exercised with caution when administered during pregnancy.
Lactation:
Cefalexin is excreted in human milk in low concentration and should be used in caution during breastfeeding.

DRUG INTERACTIONS:
Anticoagulants: Concurrent administration of cephalosporin and anticoagulants may prolong the prothrombin time.
Oral Contraceptive Pills: Other cephalosporins may affect the gut flora and may reduce the reabsorption and effect of the oral contraceptives.
Probenecid: Concomitant administration of probenecid as with other Beta lactams may inhibit the tubular secretion and may result to increased and sustained plasma levels for longer period.

ADVERSE DRUG REACTIONS:
GI: Nausea, vomiting, abdominal discomfort and dyspepsia.
Hypersensitivity Reactions: Anaphylaxis, maculopapular erythematous, urticarial, pruritus, angioedema, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis
Hematologic: Positive direct and indirect antiglobulin (Coombs' test) results, hemolytic anemia, decreased platelets, thrombocytopenia, decrease hemoglobin and hematocrit
Other Adverse Effects: Joint disorder, genital candidiasis, genital and anal pruritus, arthralgia, arthritis, vaginitis

OVERDOSE AND TREATMENT:
Overdosage:
Clinical symptoms of oral cefalexin dose may include nausea, vomiting, epigastric distress, diarrhea and hematuria.
Treatment:
It is important to protect the patient airway and support ventilation and perfusion during overdose. Drug absorption from the GIT may be decreased by administration of activated charcoal, in many cases, it is more effective than emesis or lavage. Unless 5 to 10 times the normal cefalexin dose has been ingested, gastrointestinal contamination should not necessary.

STORAGE CONDITION:
Keep out of reach of children
Store at temperatures not exceeding 30°C
Protect from light

DIRECTION FOR RECONSTITUTION:
250 mg/5mL Powder for Suspension
To make 60 mL reconstituted suspension, add approximately 43 mL of water and shake well until the powder is evenly suspended. The reconstituted suspension is stable for 7 days at room temperature and 14 days when refrigerated.

100 mg/mL Powder for Suspension (Oral Drops)
To make 10 mL, add 8 mL of water and shake well until the powder is evenly suspended. The reconstituted suspension is stable for 7 days at room temperature and 14 days when refrigerated.

AVAILABILITY:
Cefalexin monohydrate (Cephoral) 500 mg Capsule – Clear PVC/Aluminum Blister Strip x 10's (Box of 100's)
Cefalexin monohydrate (Cephoral) 250 mg/5 mL Powder for Suspension – Amber Glass Bottle with White Aluminum Cap x 60 mL (Box of 1's)
Cefalexin monohydrate (Cephoral) 100 mg/mL Powder for Suspension: (Oral Drops) – Amber Glass Bottle with White Aluminum Cap and Dropper x 10 mL (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:
Cefalexin monohydrate (Cephoral) 500 mg Capsule- DR-XY20277-B
Cefalexin monohydrate (Cephoral) 250 mg/5 mL Powder for Suspension- DR-XY20247-B
Cefalexin monohydrate (Cephoral) 100 mg/mL Powder for Suspension (Oral Drops) – DR-XY20276-B

DATE OF FIRST AUTHORIZATION:
Cefalexin monohydrate (Cephoral) 500 mg Capsule - November 11, 1996
Cefalexin monohydrate (Cephoral) 250 mg/5 mL Powder for Suspension - August 28, 1995
Cefalexin monohydrate (Cephoral) 100 mg/mL Powder for Suspension (Oral Drops) - December 22, 2000

DATE OF REVISION OF PACKAGE INSERT:
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