CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 125mg/5ml
CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 250mg/5ml
CEPHALEXIN CAPSULES 'MPI' 250MG
CEPHALEXIN TABLETS 'MPI' 500MG

NAME AND STRENGTH OF ACTIVE SUBSTANCE:

CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 125mg/5ml
Each 5ml of reconstituted suspension contains:
Cephalexin Monohydrate equivalent to Cephalexin base……125mg

CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 250mg/5ml
Each 5ml of reconstituted suspension contains:
Cephalexin Monohydrate equivalent to Cephalexin base……250mg

CEPHALEXIN CAPSULES 'MPI' 250MG
Each capsule contains:
Cephalexin Monohydrate equivalent to Cephalexin base……250mg

CEPHALEXIN TABLETS 'MPI' 500MG
Each tablet contains:
Cephalexin Monohydrate equivalent to Cephalexin base……500mg

PRODUCT DESCRIPTION:

CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 125mg/5ml
Cherry red granules with cherry flavour and sweet taste.
When reconstituted with water, the product is converted into palatable suspension for oral administration.

CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 250mg/5ml
Yellow granules with banana flavour and sweet taste.
When reconstituted with water, the product is converted into palatable suspension for oral administration.

CEPHALEXIN CAPSULES 'MPI' 250MG
A white to near white powder filled in size no.2 capsules with green cap and white body with 'MPI'/'UMED' marking.

CEPHALEXIN TABLETS 'MPI' 500MG
A fawn, oblong, scored of 17 x6.5mm tablet with 'Life' marking and a characteristic odour.

PHARMACODYNAMICS :
Cephalexin monohydrate belongs to the first generation cephalosporins. Its chemical structure is (7R)-3 methyl-7-(alpha-D-phenylglycylamino) –3-cephem-4-carboxylic acid monohydrate. The beta-lactam ring of the structure is the chemical group associated with antibacterial activity. Cephalexin is bactericidal and acts similarly to the penicillins by inhibiting synthesis of the bacterial cell wall.

PHARMACOKINETICS:
Cephalexin is almost completely absorbed from the gastrointestinal tract and produces peak plasma concentrations about 1 hour after administration. A dose of 500mg produces a mean peak plasma concentration of about 18μg per ml. If cephalexin is taken with food there is delayed and slightly reduced absorption and there may be delayed elimination from the plasma. About 10 to 15% of a dose is bound to plasma proteins. The biological half-life has been reported to range from 0.6 to at least 1.2 hours and this increases with reduced renal function. 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 1mg per ml have been achieved after a dose of 500mg. Probenecid delays urinary excretion and has been reported to increase biliary excretion. Cephalexin is widely distributed in the body but does not enter the cerebrospinal fluid in significant quantities unless the meninges are inflamed. It diffuses across the placenta and small quantities are found in the milk or nursing mothers. Therapeutically effective concentration may be found in the bile.

INDICATION:
For the treatment of infections of the respiratory tract, skin and soft tissues. Also in the treatment of ear, nose and throat, GIT and O & G infections, and gonorhoea and syphilis.

RECOMMENDED DOSAGE:
To be taken orally, preferably before food.
i) Adults: 250mg to 500mg every 6 hours for moderate infections; in severe or deep-seated infections, the dose can be increased to 3 to 6g daily.
ii) Children 6- 12 years: 250mg every 8 hours.
iii) Infants and children below 6 years: The usual dose is about 25-60mg per kg body weight per day. For severe or deep-seated infections, this should be increased to 100mg per kg body weight per day (maximum 4g/day).

ROUTE OF ADMINISTRATION:
Oral

CONTRAINDICATIONS:
Known hypersensitivity to penicillin or with known histories of allergy to any of the cephalosporins. Cephalexin was considered to be unsafe in patients with acute porphyria.

WARNINGS AND PRECAUTIONS:
1. Prolonged use results in overgrowth of resistant organisms.
2. Reduced dosage is recommended in patients with impaired kidney function.
3. Patients who have experienced severe or intermediate hypersensitivity reactions to a penicillin should not be given cephalosporin because there is cross-reactivity in 4-5% of persons.
4. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Cephalexin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Cephalexin must be discontinued immediately and appropriate alternative therapy instituted.

INTERACTIONS WITH OTHER MEDICAMENTS:
1. Combined use of a cephalosporin with an aminoglycoside enhances the renal toxicity of each.
2. The urine of patients taking cephalexin may give a false positive reaction for glucose with copper-reduction reagents.
3. Positive results to the Coomb's test have been reported with cephalexin.
4. Probenecid delays urinary excretion of cephalexin.
5. There have been isolated report of cephalexin decreasing the efficacy of oestrogen-containing oral contraceptives.

PREGNANCY AND LACTATION:
Pregnancy
The safety in pregnancy has not been established.

Lactation
It diffuses across the placenta and small quantities are found in the milk or nursing mothers. Care should be taken in nursing mothers as small quantities are found in milk of nursing mothers.

SIDE EFFECTS:
1. Allergic: hypersensitivity reaction includes skin rashes.
2. Gastrointestinal : nausea, vomiting and diarrhoea, abdominal discomfort.
3. Hematologic: rises in serum aminotransferases have been noted. Eosinophilia and neutropenia have occurred in a few patients.
4. Renal: nephrotoxicity occurs but is usually reversible.
5. Others: superinfection with resistant microorganisms particularly Candida, may follow after treatment.
6. Pseudomembranous colitis has been reported.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Symptoms:
Convulsions and other signs of CNS toxicity have been associated with high doses, especially in patients with renal failure.

Treatment: Symptomatic treatment as there is no specific antidote available.
Absorption of drug from the gastro-intestinal tract may be decreased by giving activated charcoal. Which in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten eliminination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal. Forced diuresis, peritoneal dialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cephalexin; however, it would be extremely unlikely that one of these procedures would be indicated.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
No effect

PRECLINICAL SAFETY DATA
Not applicable

INSTRUCTION FOR USE
For oral use only.

Direction for Reconstitution / Mixing of Oral Suspensions:
Add sufficient water (about 30ml distilled or boiled water, cooled to room temperature), close bottle and shake vigorously, and make up volume to 60ml mark with water. Shake well before each dose.

DOSAGE FORMS AND PACKAGING AVAILABLE:
CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 125mg/5ml
CEPHALEXIN GRANULES FOR ORAL SUSPENSION 'MPI' 250mg/5ml
Pack size : 60ml in plastic bottle (after reconstitution)

CEPHALEXIN CAPSULES 'MPI' 250MG
Blister pack: 100 x 10's

CEPHALEXIN TABLETS 'MPI' 500MG
Blister pack: 100 x 10's

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:
MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:
07/01/2022