Pharmexin®

Cephalexin

Pharmacological information

Mode of action: Pharmexin® (Cephalexin) is a first-generation cephalosporin. Its bactericidal action depends on the ability to reach and bind penicillin-binding proteins, hence inhibiting cell wall synthesis. Rapidly dividing bacteria are the most susceptible to the action of Pharmexin®.

Pharmacokinetics

Pharmexin® is almost completely absorbed from the gastrointestinal tract. Food may delay absorption but the total amount absorbed is not appreciably altered. Up to 15% of a dose is bound to plasma proteins. Plasma half-life is about 1 hour. Following doses of 250mg, 500mg and 1g, average peak serum levels of approximately 9, 18 and 32 mg/ml respectively were obtained after 1 hour. Pharmexin® is widely distributed throughout the body and reaches therapeutic concentrations in most tissues and body fluids but it does not enter the cerebro-spinal fluid in significant quantities. Pharmexin® is not metabolized and about 80% or more of a dose is excreted unchanged in the urine in the first 6 hours, some may be excreted in the bile.

Clinical information

Indications: Pharmexin® is active against most gram-positive bacteria, including beta-lactamase-producing Staphylococcus aureus and most Streptococci; exceptions include methicillin-resistant Staphylococci, and penicillin-resistant Streptococcus pneumoniae. Gram-negative bacteria coverage is limited to E. coli, Klebsiella species, and Proteus mirabilis. Pharmexin® is indicated in the treatment of bone and joint infections, otitis media, bacterial pharyngitis, bacterial pneumonia, bacterial septicemia, skin and soft tissue infections, tonsillitis, and bacterial urinary tract infections caused by susceptible organisms.

Dosage and administration

Usual adult and adolescent dose:

Antibacterial: 250-500mg orally every 6 hours.

Uncomplicated cystitis, skin and soft tissue infections and streptococcal pharyngitis: 500mg orally every 12 hours.

Usual adult prescribing limit: Up to 4g daily.

Usual pediatric dose:

Antibacterial: 6.25-25mg/kg of body weight orally every 6 hours.

Skin and soft tissue infections and streptococcal pharyngitis: 12.5-50 mg/kg of body weight orally every 12 hours. Pharmexin® may be taken on a full or empty stomach. However, taking it with food may help if gastrointestinal irritation occurs.

Contraindications

Cephalexin is contraindicated in patients with previous allergic reactions (anaphylaxis) to penicillins, penicillin derivatives, penicillamine or cephalosporins.

Warnings

Risk-benefit should be considered in case of history of bleeding disorders because Cephalexin may cause hypo-prothrombinemia, and potentially bleeding, also in case of history of gastrointestinal disease because it may cause pseudo-membranous colitis.Reduced dosage is recommended in renal function impairment.

Precautions

Cross-sensitivity: There is evidence of partial cross-allergenicity of the penicillins and the cephalosporins. Caution is recommended when cephalosporins are administered to patients with a history of penicillin anaphylaxis, since anaphylaxis may also occur after cephalosporin administration.

Use in pregnancy and lactation: FDA Pregnancy Category B. Cephalexin crosses the placenta. Adequate and well-controlled studies in humans have not been done. However, studies in animals have not shown that Cephalexin causes adverse effects on the fetus. Safety during pregnancy in humans has not been established so it should be used only if clearly needed during pregnancy. Cephalexin is excreted in low concentrations in breast milk. However, problems in humans have not been documented, but caution should be exercised when administered to a nursing woman.

Use in pediatrics and geriatrics: No pediatrics- or geriatrics- specific problems have been documented to date. However, age-related decrease in renal function in elderly patients require dosage or dosing interval adjustment; and lower metabolic and /or renal clearance in pediatrics result in prolongation of t1/2.

Drug interactions

- Hypoprothrombinemia induced by large doses of cephalosporin may increase the risk of hemorrhage when used concurrently with platelet aggregation inhibitors.
- Probenecid decreases renal tubular secretion resulting in increased serum concentration and prolonged elimination t1/2.

Diagnostic interference

Interference with diagnostic test results:

(antiglobulin) tests in patients receiving high dosage of Cephalexin or in neonates whose mothers received Cephalexin before delivery. False-positive or falsely elevated test results with copper sulfate tests. Prothrombin time may be prolonged.

Interference with physiology/laboratory test results: ALT,AST, serum bilirubin, serum LDH, BUN or serum creatinine may be increased.

Side effects

More frequent side effects: Oral candidiasis, gastrointestinal reactions, vaginal candidiasis.

Less frequent or rare side effects: Hypoprothrombinemia, pseudomembranous colitis, allergic reactions specifically anaphylaxis, erythema multiforme, hemolytic anemia, hypersensitivity, renal dysfunction, serum sickness-like reactions, and seizures especially in high doses or renal impairment.

Overdose

Symptoms of overdose may include nausea, vomiting, epigastric distress, diarrhea and hematuria. Treatment of over-dose should be supportive and symptomatic as there is no specific antidote.

Pharmaceutical information

How supplied:

Pharmexin® F/C tabs.: 1000mg Cephalexin(monohydrate) / tab.
Pharmexin® F/C tabs.: 500mg Cephalexin(monohydrate) / tab.
Pharmexin® suspension: 125mg Cephalexin (monohydrate) /5ml after reconstitution.
Pharmexin® suspension: 250mg Cephalexin (monohydrate) /5ml after reconstitution.
Pharmexin® Caps.: 250mg Cephalexin (monohydrate) / cap.
Pharmexin® Caps.: 500mg Cephalexin (monohydrate) / cap.

(This is a Medicament - Keep medicaments out of the reach of children)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method for use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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