

# Solvocef® (Cephalexin) Capsules 500 mg

سولوو سیف  
(سیفالیکسن)  
کیپسولز ۵۰۰ ملی گرام

#### COMPOSITION:

Each capsule contains:  
Cephalexin (U.S.P.) ..... 500 mg.  
Product Complies U.S.P. Specs.

#### DESCRIPTION:

SOLVOCEF (Cephalexin) is a semisynthetic cephalosporin antibiotic intended for oral administration. It is 7-(D- $\alpha$ -amino- $\alpha$ -phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid, monohydrate. The molecular formula of Cephalexin is  $C_{16}H_{17}N_3O_2S_2H_2O$  and the molecular weight is 365.41.

#### PHARMACOLOGY:

SOLVOCEF (Cephalexin) is acid stable and may be given without regard to meals. It is rapidly absorbed after oral administration. Following dose of 500 mg, average peak serum level of approximately 18 mg/l were obtained at 1 hour. Measurable level was present 6 hours after administration. Cephalexin is excreted in the urine by glomerular filtration and tubular secretion. Studies showed that over 90% of the drug was excreted unchanged in the urine within 8 hours. During this period, peak urine concentrations was approximately 2.2 g/l.

#### MICROBIOLOGY:

*In vitro* tests demonstrate that the cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. SOLVOCEF (Cephalexin) is active against the following organisms *in vitro*:

- Beta-haemolytic streptococci
- Staphylococci, including coagulase-positive, coagulase-negative, and penicillinase-producing strains
- Streptococcus (Diplococcus) pneumoniae
- Escherichia coli
- Proteus mirabilis
- Klebsiella sp.
- Haemophilus influenzae
- Moraxella (Branhamella) catarrhalis

#### INDICATIONS:

SOLVOCEF (Cephalexin) is indicated in the treatment of following infections when caused by susceptible strains of the designated microorganisms:

- Dental infections
- Bacterial sinusitis
- Respiratory tract infections
- Otitis media
- Skin and skin-structure infections
- Bone infections
- Genitourinary tract infections, including acute prostatitis

#### DOSAGE AND ADMINISTRATION:

SOLVOCEF (Cephalexin) capsule 500 mg is administered orally.

**Adults-** The adult dosage ranges from 1 to 4 g daily in divided doses. The usual adult dose is 500 mg 12 hourly or 250 mg 6 hourly or as directed by the physician.

#### CONTRAINDICATION:

SOLVOCEF (Cephalexin) is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

#### WARNINGS:

Before SOLVOCEF (Cephalexin) therapy is instituted, careful inquiry should be made concerning previous hypersensitivity reactions to cephalosporins and penicillin. Serious acute hypersensitivity reactions may require epinephrine and other emergency measures.

#### PRECAUTIONS:

**General -** Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to SOLVOCEF (Cephalexin) occurs, the drug should be discontinued and the patient treated with the usual agents (e.g. epinephrine or other Pressor amines, antihistamines, or corticosteroids). Prolonged use of SOLVOCEF (Cephalexin) may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. SOLVOCEF (Cephalexin) should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made. As a result of administration of SOLVOCEF (Cephalexin), a false-positive reaction for glucose in the urine may occur. Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

**Usage in pregnancy-** Safety of this product for use during pregnancy has not been established. SOLVOCEF (Cephalexin) should be used during pregnancy only if benefits outweigh the risk.

**Nursing mothers -** The excretion of Cephalexin in the breast milk increases up to 4 hours after a 500 mg dose; the drug reaches a maximum level of 4 mg/l, then decreases gradually, and disappears 8 hours after administration. Caution should be exercised when SOLVOCEF (Cephalexin) is administered to a nursing woman.

#### ADVERSE REACTIONS:

Gastrointestinal symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea, vomiting, diarrhoea, dyspepsia and abdominal pain have been reported. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

**Hypersensitivity-** Allergic reactions in the form of rash, urticaria, angioedema, have been observed. These reactions usually subside upon discontinuation of the drug. Anaphylaxis has also been reported. Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorder.

#### OVERDOSAGE:

**Signs and symptoms-** Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhoea and hamaturia.

**Treatment-** In managing overdose, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

#### HOW SUPPLIED:

SOLVOCEF 500 mg capsule is available in blister pack of 1 x 12's.

Store below 30°C in a dry place, protect from light.

To be dispensed on the prescription of a registered

medical practitioner only.

Keep out of the reach of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر

رہتی ہے، ہچا کر خشک جگہ پر رکھیں۔

صرف ریسیڈ ڈاکٹر کے نسخے پر فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

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