1. NAME OF THE MEDICINAL PRODUCT:
Cefexol DS Suspension 200mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Cefexol DS Suspension 200mg/5ml
When reconstituted as directed:
Each 5 ml contains:
Cefixime (as Trihydrate) …..200 mg

Cefexol DS Suspension 200mg/5ml
Sugar Pharma Grade (Dry Suspension Grade), Xanthan Gum, Sodium Benzoate, Aerosil 200 (Colloidal Silicone Dioxide) , Encapsulated Banana Flavor

Description:

Cefexol DS Suspension 200mg/5ml
White to off-white, dry granular powder gives off-white colored, banana-flavored suspension when reconstituted with water.

3. PHARMACEUTICAL FORM:
Suspension

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications

CEFEXOL is indicated in the following infections:
In Upper Respiratory Tract Infections e.g.; sinusitis, pharyngitis, laryngitis, tonsillitis & otitis media.
In Lower Respiratory Tract Infections e.g.; acute bronchitis, acute exacerbations of chronic bronchitis, and Pneumonia.
Gastrointestinal tract infections e.g.; enteric fever especially for Multi-Drug Resistant (MDR) typhoid.
In Urinary Tract Infections e.g.; cystitis, cystourethritis, cervicitis, uncomplicated pyelonephritis, and uncomplicated gonorrhea.

4.2 Posology and method of administration

Absorption of Cefixime is not significantly modified by the presence of food. The usual course of treatment is 5-14 days.
Adults & Children Over 12 Years: The usual recommended adult dosage is 400mg daily to be administered as a single dose or in two divided doses.
Children Below 12 Years: The recommended dosage for children is 8mg/kg/day administered as single dose. The following is suggested as a general guide for prescribing in children.

The dosage in children aged 6 months to one year should be calculated on 8mg/kg/day according to body weight.

Dosage in Renal Impairment: Cefixime doses should be reduced in patients with impaired renal function. Normal dose may be given in patients with creatinine clearance of 20ml/min or greater.

Directions For Preparation: Shake bottle of powder well to loosen the powder. Add half of water (10ml Approx.) from the bottle of Purified Water, to the bottle of powder and close the cap and shake. After this, add remaining Purified Water (10ml Approx.) to the bottle of powder. Close the cap and shake well till the oral suspension prepared for the use. Prepared suspension should be utilized within one week. Shake well before use.

4.3 Contraindications:
Patients with known hypersensitivity to cephalosporin antibiotics.

4.4 Special warnings and precautions for use:
Cephalosporin should be given with caution to penicillin sensitive patients.

4.5 Interaction with other medicinal products and other forms of interaction:
No significant drug interactions have been reported to date.

4.6. Fertility, Pregnancy and Lactation

Pregnancy:
Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 40 times the human dose and have revealed no evidence of harm to the fetus due to cefixime. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Fertility:
Cefixime has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Lactation:
It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

4.7. Effects on ability to drive and use machines:
Not found

4.8. Undesirable effects:
Cefixime is generally well tolerated. The most frequently reported side effects of Cefixime are gastrointestinal disturbances, specially diarrhea. Other side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting, flatulence, headache & dizziness.

4.9. Overdose:
There is no experience with overdoses of Cefixime. Adverse reactions seen at dose levels up to 2g Cefixime in normal subject.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamics properties and Pharmacokinetic properties:

Absorption:
The absolute oral bioavailability of cefixime is in the range of 22-54 %. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard to meals.

Distribution:
Serum protein binding is well characterised for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30 %. Protein binding of cefixime is only concentration dependent in human serum at very high concentrations which are not seen following clinical dosing.
From in vitro studies, serum or urine concentrations of 1 mg/L or greater were considered to be adequate for most common pathogens against which cefixime is active. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mg/L. Little or no accumulation of cefixime occurs following multiple dosing.

Metabolism and elimination:
Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine. Transfer of 14C-labelled cefixime from lactating rats to their nursing offspring through breast milk was quantitatively small (approximately 1.5 % of the mothers' body content of cefixime in the pup). No data are available on the secretion of cefixime in human breast milk. Placental transfer of cefixime was small in pregnant rats dosed with labeled cefixime.

Special age groups:
The pharmacokinetics of cefixime in healthy elderly (age > 64 years) and young volunteers (11-35) compared the administration of 400 mg doses once daily for 5 days. Mean Cmax and AUC values were slightly greater in the elderly. Elderlypatients may be given the same dose as the general population.

5.2 Preclinical safety data:

Carcinogenesis, Mutagenesis, Impairment of Fertility
Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage in vitro and did not exhibit clastogenic potential in vivo in the mouse micronucleus test. In rats. Fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

- Sugar Pharma Grade (Dry Suspension Grade)
- Xanthan Gum
- Sodium Benzoate
- Aerosil 200 (Colloidal Silicone Dioxide)
- Encapsulated Banana Flavor

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

Cefexol DS Suspension 200mg/5ml ----24 months

6.4 Special precautions for storage:

Store below 30°C.
Protect from heat and light.
Keep out of the reach of children.
For oral use only. Do not freeze

6.5 Nature and contents of container:

Cefexol DS Suspension 200mg/5ml ---- Cefexol DS Suspension containing granular powder for preparation of 30 ml suspension.

6.6 Special precautions for disposal and other handling:

No special requirements.

7. MARKETING AUTHORISATION HOLDER:

Nabiqasim Industries (Pvt.) Ltd.
17/24, Korangi Industrial Area.
Karachi – Pakistan.

8. MARKETING AUTHORISATION NUMBER:

Cefexol DS Suspension 200mg/5ml ----034464

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION:

Cefexol DS Suspension 200mg/5ml ---- 17-02-2005