SUMMARY PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Cefexol Capsule 400mg
Cefexol Suspension 100mg/5ml
Cefexol DS Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cefexol Capsule 400mg
Each capsule contains:
Cefixime USP.....400mg

Cefexol Suspension 100mg/5ml
When reconstituted as directed:
Each 5 ml contains:
Cefixime (as Trihydrate) .....100 mg

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, Suspension

Description:

Cefexol Capsule 400mg
Hard gelatin capsule No. "0" with olive green opaque cap / olive green opaque body with "NQ" printed on cap and "CEFEXOL" printed on body containing off-white dry granular powder.

Cefexol Suspension 100mg/5ml
White to off-white, dry granular powder gives off-white colored, orange and strawberry flavored suspension when reconstituted with water.

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

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications

CEFEXOL is indicated in 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 specially 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. Following is suggested as a general guide for prescribing in children.

Age	Cefixime/ Day	CEFEXOL SUSPENSION	CEFEXOL DS SUSPENSION
1-4 years	100mg	1 teaspoonful	1/2 teaspoon
5-9 years	200mg	2 teaspoonful	1 teaspoonful
10-12 years	300mg	3 teaspoonful	1 1/2 teaspoon

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

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

As with other Cephalosporins, the bactericidal action of Cefixime results from inhibition of cell wall synthesis. Cefixime is stable in the presence of certain beta-lactamase enzymes. As a result, certain organisms resistant to Penicillins and some Cephalosporins due to the presence of beta-lactamase may be susceptible to Cefixime.

5.2 Pharmacokinetics

Food reduces the absorption following administration of the capsule by approximately 15 % based on AUC and 25% based on Cmax. Peak serum concentration occur between 3 and 8 hours following oral administration of a single 400 mg capsule.

5.3 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

Cefexol Capsule 400mg Magnesium Stearate

Cefexol Suspension 100mg/5ml
Sugar Pharma Grade (Dry Suspension Grade), Sodium Benzoate ,Sodium Carboxy Methyl Cellulose (Scmc) , Aerosil 200 (Colloidal Silicone Dioxide), Encapsulated Orange Flavour Encapsulated Strawberry Flavour
Cefexol DS Suspension 200mg/5ml
Sugar Pharma Grade (Dry Suspension Grade) , Xanthan Gum ,Sodium Benzoate ,Aerosil 200 (Colloidal Silicone Dioxide) , Encapsulated Banana Flavour

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

Cefexol Capsule 400mg 24 months
Cefexol Suspension 100mg/5ml 36 months

Cefexol DS Suspension 200mg/5ml 24 months

6.4 Special precautions for storage:

Store below 30^0C.
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 Capsule 400mg Alu Alu Blister pack contains 5 capsules.
Cefexol Suspension 100mg/5ml ---- Cefexol Suspension containing granular powder for preparation of 30 ml suspension.
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:

H2022/CTD8261/15221

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION

Cefexol Capsule 400mg 30-03-2000
Cefexol Suspension 100mg/5ml 30-03-2000
Cefexol DS Suspension 200mg/5ml 17-02-2005

10. DATE OF REVISION OF THE TEXT:

May-2018

11. DOSIMETRY

Not applicable