Cefixime Neocef
(Cefixime)

AtralCipan

630

Qualitative and quantitative composition

Cefixime Neocef 400mg coated tablets
Per coated tablet: Cefixime (as trihydrate) 400mg

Cefixime Neocef 100mg/5ml powder for oral suspension
Per 5ml: Cefixime (as trihydrate) 100mg

Pharmaceutical form and route of administration

Cefixime Neocef 400mg coated tablets and **Cefixime Neocef** 100mg/5ml powder for oral suspension for oral administration.

Pharmacotherapeutic group: Antibiotics - third generation cephalosporins

Marketing Authorization Holder

LABORATÓRIOS ATRAL, S.A.
Vala do Carregado
2600 – 726 Castanheira do Ribatejo - Portugal

Therapeutic indications

Cefixime Neocef is used orally in adults and children for the treatment of the following infections:

- upper respiratory tract infections: pharyngitis, tonsillitis, otitis media
- lower respiratory tract infections: pneumonia, acute and chronic bronchitis
- urinary tract infections: acute cystitis, cystourethritis, acute pyelonephritis

Cefixime Neocef is usually active, *in vitro*, against *Streptococcus pneumoniae, Streptococcus b-haemolyticus* Lancefield's group A, *Streptococcus* group B and *Streptococcus* group C, F and G.
Clinical efficacy of cefixime has been demonstrated in infections caused by commonly occuring pathogens as *Escherichia coli, Proteus mirabilis, Klebsiella, Haemophilus influenzae, Moraxella catarrhalis* and different species of *Enterobacter.*

Contraindications

Cefixime Neocef is contraindicated in patients with known hypersensitivity to cephalosporins.

Undesirable effects

Cefixime Neocef is generally well tolerated; the majority of the undesirable effects are transient and mild to moderate in severity.
The most frequent undesirable effects are: loose stools or diarrhea, abdominal pain, dyspepsia, flatulence and nauseas. Cases of pseudomembranous colitis have been described (in less than 2% of patients).
Cases of headache, dizziness, indisposition and fatigue have also been reported.
Hypersensitivity reactions have been reported in about 7% of the patients receiving cefixime and include rash, urticaria, pruritus and arthralgia.
Thrombocytopenia, leukopenia, eosinophilia and decreased hemoglobin concentration and hematocrit have been reported in about 2% of patients.
Changes in hepatic and renal tests have occasionally been described.

Interaction with other medicinal products and other forms of interaction

Concomitant administration of cefixime and probenecid increases serum cefixime concentrations and decreases renal clearance and volume of distribution of the drug.
In one *in vitro* study, acetylsalicylic acid apparently displaced cefixime from protein binding sites, resulting in more than a 50% increase in concentrations of free cefixime.
False-positive results in urinary glucose determinations using cupric reagents may be observed.
Coomb's test results may be false–positive.

Special precautions for use

Cefixime Neocef should be used with caution in individuals with hypersensitivity to penicillins, as well in individuals with a history of allergy to any of the excipients.
Cefixime Neocef should be used with caution in patients with a history of gastrointestinal disease, particularly colitis. Cases of pseudomembranous colitis associated with the use of antibiotics have been reported, by which it should be considered as a differential diagnosis in patients who develop diarrhea during cefixime therapy.
Aspartame, excipient present in **Cefixime Neocef** 100mg/5ml powder oral suspension should not be administered to patients with phenylketonuria. It causes hypersensitivity and is contraindicated in children under 3 years.
Cefixime Neocef 100mg/5ml powder for oral suspension contains **sucrose**, which present a risk of dental caries and is harmful for patients with glucose-galactose malabsorption syndrome, fructose intolerance or sucrase-isomaltase deficiency.

Effects on pregnant women, lactating infants, children, elderly and patients with special pathologies

There are no adequate and controlled studies to date using cefixime in pregnant women and the drug should be used during pregnancy only when clearly needed.
Cefixime Neocef should be used with caution in nursing women and consideration should be given to discontinuing nursing during therapy with the drug.

630

Safety and efficacy of cefixime in children younger than 6 months of age have not been established. Diarrhea has been reported in 15% of children 6 months to 13 years. Because renal function decreases with age and may be impaired in geriatric patients, the adjustment of **Cefixime Neocef** dosage may be necessary in this age group.

Effects on the ability to drive and use machines
Not applicable.

List of Excipients
Cefixime Neocef 100mg/5ml powder for oral suspension
Sucrose
Sodium lauryl sulphate
Sodium benzoate
Hypromellose
Xanthan gum
Aspartame
Fruit essences

Cefixime Neocef 400mg coated tablets
Microcrystalline cellulose
Starch maize pregelatinized
Calcium monohydrogen phosphate
Sodium carboxymethyl starch
Magnesium stearate
Hypromellose
Titanium dioxide
Macrogol 400
Magrocol 6000
Cellulose acetate phthalate

Posology and method of administration
Oral administration.
The absorption of **Cefixime Neocef** is not modified in presence of food, so that **Cefixime Neocef** can be administered with meals.

Adults and children over 12 years (or more than 50kg of body weight):

400mg daily, administered as a single daily dose or in two daily administrations of 200mg.

Children under 2 years:
8mg/kg/day

When suspension is used:
- from 2 to 4 years: 5ml/day
- from 5 to 8 years:10ml/day
- from 9 to 12 years: 15 ml/day

This dose may be given as a single daily dose or in two administrations.

Patients with renal impairment:
In patients with creatinine clearance equal or higher than 20ml/minute, the doses are indicated above.
In patients with creatinine clearance less than 20 ml/minute, do not exceed 200mg/day.

Actions in case of overdose and/or intoxication
In healthy adults who received 2g of cefixime as a single dose, the undesirable effects were similar to those seen with usual doses of the drug and included mild to moderate adverse gastrointestinal effects.
In case of overdosage, the stomach should be emptied by gastric lavage.
Cefixime is not removed in clinically important quantities by hemodialysis or peritoneal dialysis.

Presentation
Coated tablets – containing 400mg of cefixime (as trihydrate). Packs of 1, 6, 8 and 12 units.
Powder for oral suspension – containing per 5ml of suspension 100mg of cefixime (as trihydrate). Packs of 60ml, 100ml and 120ml.
Not all pack sizes may be marketed.

Warning: the powder for oral suspension contains sucrose and aspartame.

Special precautions for storage
Coated tablets - Store below 25°C in a dry place
Powder for oral suspension - Store below 25°C, in a dry place protected from light

If you notice any undesirable effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Please verify the shelf life stated on the label
Keep out of the reach and sight of children

This leaflet was last reviewed on September/2012

34852561
Ref.: FI-01-OUT-12