PROFESSIONAL INFORMATION

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

CEFPODOXIME 100 ADCO (film-coated tablet)

CEFPODOXIME 200 ADCO (film-coated tablet)

COMPOSITION

CEFPODOXIME 100 ADCO: Each tablet contains 100 mg of cefpodoxime as cefpodoxime proxetil.

CEFPODOXIME 200 ADCO: Each tablet contains 200 mg of cefpodoxime as cefpodoxime proxetil.

Excipients:

Carmellose calcium, lactose monohydrate, hydroxypropyl methylcellulose (hypromellose 6 Cp), low substituted hydroxypropyl cellulose, magnesium stearate, sodium lauryl sulphate, talc, titanium dioxide (C.I. No. 77891)

Contains sugar:

CEFPODOXIME 100 ADCO:

Lactose monohydrate 9 mg per tablet

CEFPODOXIME 200 ADCO:

Lactose monohydrate 18 mg per tablet

CATEGORY AND CLASS

A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Cefpodoxime proxetil is the prodrug of the bactericidal antibiotic cefpodoxime. Cefpodoxime is a semisynthetic beta-lactam antibiotic, belonging to the third generation oral cephalosporins which

has *in vitro* bactericidal activity against a wide range of Gram-negative and Gram-positive organisms. It inhibits the biosynthesis of the bacterial cell wall, enhanced by a high affinity for proteins at the cytoplasmic membrane.

In vitro sensitivity does not necessarily imply *in vivo* efficacy. The following organisms are sensitive strains. Sensitivity tests must however be performed.

Gram-positive organisms

- *Streptococcus pneumoniae.*
- Streptococci of Groups A (*S. pyogenes*), B (*S. agalactiae*), C, F and G.
- Other streptococci (*S. mitis*, *S. sanguis* and *S. salivarius*).
- *Propionibacterium acnes.*
- *Corynebacterium diphtheriae.*
- Methicillin-sensitive *S. aureus*, penicillinase and non-penicillinase producing strains.

Gram-negative organisms

- *Haemophilus influenzae*, beta-lactamase and non beta-lactamase producing strains.
- *Haemophilus para-influenzae*, beta-Iactamase and non beta-lactamase producing strains.
- *Moraxella catarrhalis* (*Branhamella catarrhalis*), beta-lactamase and non beta-Iactamase producing strains.
- *Neisseria gonorrhoeae*, beta-lactamase and non beta-Iactamase producing strains.
- *Escherichia coli.*
- *Klebsiella pneumoniae, Klebsiella oxytoca*.

The following organisms are not sensitive: Group D streptococci, Methicillin-resistant staphylococci (*S. aureus* and *S. epidermidis*), *Staphylococcus saprophyticus*, *Corynebacteria*, groups J and K, *Listeria monocytogenes*, *Pseudomonas aeruginosa* and *Pseudomonas* spp., *Acinetobacter baumanii*, *Clostridium difficile*, *Bacteroides fragilis* and related species.

Pharmacokinetic properties

Absorption

Cefpodoxime proxetil is administered orally and is absorbed in the gastrointestinal tract and then hydrolysed by non-specific esterases to the active metabolite cefpodoxime.

The bioavailability of cefpodoxime is increased when given with food or when the gastric pH is reduced. Bioavailability is reduced when the gastric pH is increased.

Distribution

Cefpodoxime diffuses in the pleural fluid, bronchial mucosa, lung parenchyma and tonsils.

Adults

The maximum plasma concentration (C_{max}) obtained following oral administration of 100 mg of cefpodoxime is 1 to 1,2 mg/l and 2,2 to 2,5 mg/l after 200 mg cefpodoxime. The time to reach maximum concentration (T_{max}) is between 2 to 3 hours. About 40 % of cefpodoxime is bound to plasma proteins mainly albumin.

Children

The time taken to reach maximum concentration (T_{max}) is 2 to 4 hours.

Elimination

The elimination half-life of cefpodoxime is 2,4 hours. Eighty percent (80 %) of cefpodoxime is excreted unchanged in the urine.

INDICATIONS

Adults

CEFPODOXIME ADCO is indicated for short-term treatment of upper and lower respiratory tract infections due to susceptible micro-organisms:

- Acute bronchitis, relapses or acute exacerbations of chronic bronchitis and bacterial pneumonia.
- Pharyngitis and tonsillitis.
- Community-acquired bronchopneumonia.
- Acute sinusitis.

Children

CEFPODOXIME ADCO is indicated for short-term treatment of infections due to susceptible micro-organisms:

Upper and lower respiratory tract infections:

- Otitis media.

- Tonsillitis and pharyngitis.
- Pneumonia.

CONTRAINDICATIONS

CEFPODOXIME ADCO is contraindicated in:

- Patients with hypersensitivity to cefpodoxime or to any of the excipients in CEFPODOXIME ADCO (see COMPOSITION).
- Children below 1 year of age (see DOSAGE AND DIRECTIONS FOR USE).

WARNINGS AND SPECIAL PRECAUTIONS

Before initiating therapy with CEFPODOXIME ADCO careful enquiry should be made concerning previous hypersensitivity reactions to penicillins and other beta-lactams as cross sensitivity occurs between penicillins and cephalosporins (see CONTRAINDICATIONS). Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on CEFPODOXIME ADCO. If an allergic reaction occurs CEFPODOXIME ADCO should be discontinued.

CEFPODOXIME ADCO should be used with care in patients with renal impairment (see DOSAGE AND DIRECTIONS FOR USE).

Caution should be exercised in patients with a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or antibiotic associated colitis.

A positive antiglobulin (Coombs) test has been reported during treatment with cephalosporins.

Severe and persistent watery diarrhoea which occurs during treatment or the first weeks after treatment may be a result of antibiotic related pseudomembranous enterocolitis caused by *Clostridium difficile*. The diagnosis of this rare and possibly fatal condition should be confirmed by colonoscopy or histology. CEFPODOXIME ADCO should be discontinued if symptoms suggestive of pseudomembranous enterocolitis arise and appropriate antibiotic therapy should be initiated.

Effects on ability to drive and use machines

Since adverse reactions such as dizziness have been reported in patients receiving CEFPODOXIME ADCO, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that CEFPODOXIME ADCO does not adversely affect their ability to do so (see SIDE EFFECTS).

Excipients:

CEFPODOXIME ADCO contains lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption should not take CEFPODOXIME ADCO.

INTERACTIONS

Absorption of CEFPODOXIME ADCO is decreased by concurrent ingestion of antacids or histamine H_2-receptor antagonists such as ranitidine. Probenecid reduces the renal excretion of CEFPODOXIME ADCO.

HUMAN REPRODUCTION

Safety and efficacy of CEFPODOXIME ADCO has not been established in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

Each CEFPODOXIME 100 ADCO tablet contains 100 mg of cefpodoxime.
Each CEFPODOXIME 200 ADCO tablet contains 200 mg of cefpodoxime.

Adults

Tonsillitis, pharyngitis and acute bronchitis

One CEFPODOXIME 100 ADCO tablet every 12 hours with meals (200 mg/day).
In the treatment of beta-haemolytic streptococcal infections, the dose has to be administered for at least 10 days.

Acute sinusitis, acute exacerbations of chronic bronchitis, pneumonia

Two CEFPODOXIME 100 ADCO tablets or one CEFPODOXIME 200 ADCO tablet every 12 hours with meals (400 mg/day).

Elderly patients

Dosage adjustment is not necessary where renal function is normal.

Renal insufficiency in adults and children

The following dosing schedule is proposed:

Creatinine clearance	Dosage
> 40 ml/minute	No change
< 40 ml/minute	
- 10 to 39 ml/minute	½ tablet daily (50 mg)
- < 10 ml/minute	½ tablet (50 mg) every second day

For patients undergoing haemodialysis the dosage should be administered after each dialysis session.

Children

The dosage depends on the weight of the child being treated. The average dose is 8 mg/kg/day administered in two doses at 12 hourly intervals with meals.

There is insufficient experience with CEFPODOXIME ADCO to make dosage recommendations for children less than 1 year of age.

SIDE EFFECTS

Blood and lymphatic system disorders

Less frequent: Thrombocytosis, leucopenia, eosinophilia, reduction of haemoglobin, neutropenia, thrombocytopenia, agranulocytosis, haemolytic anaemia with a positive Coombs test

Immune system disorders

Less frequent: Skin rashes, urticaria, pruritus, purpura, eosinophilia, fever, reactions resembling serum sickness, cutaneous eruptions, bullous eruptions, anaphylactic reactions such as bronchospasm, angioedema, anaphylactic shock, erythema multiforme, Stevens-Johnson syndrome

Nervous system disorder

Frequency unknown: Headache, dizzy sensations, paraesthesia, asthenia, malaise

Ear and labyrinth disorders

Frequency unknown: Tinnitus

Gastrointestinal disorders

Less frequent: Nausea, vomiting, flatulence, abdominal pains, diarrhoea

Hepato-biliary disorders

Less frequent: Elevated aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase, hepatitis, cholestasis

Renal and urinary disorders

Frequency unknown: Increase in blood urea and creatinine

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

In cases of overdosage, particularly in patients with renal insufficiency, there is a risk of reversible encephalopathy for several cephalosporins. Convulsions have also been reported with very high doses especially in patients with renal impairment.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

White to off-white, round, biconvex film-coated tablets, with either “100” or “200” debossed on one side and plain on the other side.

PRESENTATION

CEFPODOXIME 100 ADCO and CEFPODOXIME 200 ADCO: 10 tablets are packed in a blister, using aluminium lidding foil and silver cold form aluminium/aluminium laminated foil.
The blister strips are packed in rigid cardboard cartons.

PROFESSIONAL INFORMATION

STORAGE INSTRUCTIONS

Store at or below 25 °C, protected from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

CEFPODOXIME 100 ADCO: 42/20.1.1/0388

CEFPODOXIME 200 ADCO: 42/20.1.1/0389

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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