SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

CEFPODOXIME 100 ADCO, 100 mg, film-coated tablets

CEFPODOXIME 200 ADCO, 200 mg, film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CEFPODOXIME 100 ADCO

Each film-coated tablet contains cefpodoxime proxetil equivalent to 100 mg cefpodoxime.

Contains sugar: lactose monohydrate 9 mg per film-coated tablet.

CEFPODOXIME 200 ADCO

Each film-coated tablet contains cefpodoxime proxetil equivalent to 200 mg cefpodoxime.

Contains sugar: lactose monohydrate 18 mg per film-coated tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

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

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults

CEFPODOXIME ADCO is indicated for short-term treatment of upper and lower respiratory tract infections due to susceptible micro-organisms (sensitivity tests must be performed):

- Acute bronchitis due to: *Haemophilus influenzae, Streptococcus pneumoniae, Moraxella catarrhalis*.
- Pharyngitis and tonsillitis due to: *Streptococcus pyogenes*.
- Acute exacerbations of chronic bronchitis due to: *Haemophilus influenzae, Streptococcus pneumoniae, Moraxella catarrhalis*.

- Bacterial pneumonia and community-acquired bronchopneumonia due to: *Haemophilus influenzae, Streptococcus pneumoniae, Moraxella catarrhalis*.
- Acute sinusitis due to: *Haemophilus influenzae* (non-typeable), *Streptococcus pneumoniae*, methicillin-sensitive *Staphylococcus aureus, Moraxella catarrhalis*.

4.2 Posology and method of administration

Posology

Adults

Tonsillitis, pharyngitis and acute bronchitis

One CEFPODOXIME 100 ADCO film-coated tablet (100 mg) every 12 hours with meals (200 mg/day).

As is the case with all beta-lactam antibiotics in the treatment of beta-haemolytic streptococcal infections, a therapeutic dose has to be administered for at least 10 days.

Acute sinusitis, acute exacerbations of chronic bronchitis, pneumonia

One CEFPODOXIME 200 ADCO film-coated tablet (200 mg) every 12 hours with meals (400 mg/day).

Special populations

Elderly population

Where renal function is normal, it is not necessary to adjust the dose.

Renal impairment

When the creatinine clearance is above 40 ml/min, it is not necessary to adjust the dose.

For values below 40 ml/min, the daily dosage regimen should be reduced by half and administered:

- as a single daily dose for values 10-39 ml/min,
- every second day for values below 10 ml/min,
- and after each dialysis session for haemodialysis patients.

A cefpodoxime suspension or alternative dosage form may be more appropriate for dosages below 100 mg.

Hepatic impairment

No dosage adjustment necessary.

Paediatric population

CEFPODOXIME ADCO film-coated tablets are not suitable for children who are unable to swallow tablets.

A cefpodoxime suspension or alternative dosage form may be more appropriate for paediatric use.

Method of administration

Oral.

The film-coated tablet should not be broken or chewed because of bad taste.

4.3 Contraindications

CEFPODOXIME ADCO is contraindicated in:

- Hypersensitivity to cefpodoxime or to any of the excipients listed in section 6.1.
- Children below 1 year of age.
- Known sensitivity to cephalosporin antibiotics (see section 4.4).

4.4 Special warnings and precautions for use

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 section 4.3). 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. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see section 4.8).

CEFPODOXIME ADCO should be used with care in patients with renal impairment (see section 4.2). Changes in renal function have been observed with antibiotics of the same class as CEFPODOXIME ADCO, particularly when given concurrently with potentially nephrotoxic agents such as aminoglycosides and/or potent diuretics. In such cases, renal function should be monitored.

Convulsions have also been reported with very high doses, especially in patients with renal impairment (see section 4.9).

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. Screening of faeces for this pathogen, and its cytotoxin is the best way to diagnose *Clostridium difficile* associated disease. CEFPODOXIME ADCO should be discontinued if symptoms suggestive of pseudomembranous enterocolitis arise and appropriate antibiotic therapy should be initiated.

Superinfection

The use of CEFPODOXIME ADCO, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken (see section 4.8).

Elderly population

CEFPODOXIME ADCO may be used at the normal recommended dosage in elderly patients even with mild to moderate renal impairment; however, appropriate modification in dosage is advised in patients with severe renal impairment (see section 4.2).

Lactose

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take CEFPODOXIME ADCO, as the tablets contain lactose.

Paediatric population

No paediatric-specific problems have been documented with the use of cefpodoxime proxetil to date. The safety and efficacy of CEFPODOXIME ADCO have not been established in children under one year of age (see section 4.3)

4.5 Interactions with other medicines and other forms of interaction

Absorption of CEFPODOXIME ADCO is decreased by concurrent ingestion of antacids or histamine H2-receptor antagonists such as ranitidine. Probenecid reduces the renal excretion of CEFPODOXIME ADCO.

The bioavailability of CEFPODOXIME ADCO is increased if the product is administered during meals (acid pH).

CEFPODOXIME ADCO potentially enhances the anticoagulant effect of warfarin and reduces the contraceptive effect of oestrogens.

Cases showing development of a positive Coombs' test have been reported (see section 4.4).

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breastfeeding

Safety and efficacy of CEFPODOXIME ADCO has not been established in breastfeeding.
Since CEFPODOXIME ADCO is excreted in human breast milk, either breastfeeding or treatment of the mother should be discontinued in mothers who are breastfeeding their infants.

Fertility

No data available.

4.7 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 section 4.8).

4.8 Undesirable effects

a. Summary of the safety profile

Common adverse reactions include eosinophilia, abdominal pain, nausea, vomiting and diarrhoea.

b. Tabulated list of adverse reactions

System Organ Class	**Frequent (≥ 1/100 to <1/10)**	**Less frequent (≥ 1/1 000 to < 1/100)**	**Frequency not known**
Infections and infestations		Superinfections, overgrowth of non-susceptible organisms (see section 4.4).	
Blood and lymphatic system disorders	Eosinophilia	Thrombocytosis, leukopenia, reduction of haemoglobin, neutropenia,	

		thrombocytopenia, agranulocytosis, haemolytic anaemia with a positive Coombs test.	
Immune system disorders		Anaphylactic reactions e.g. angioedema, bronchospasm, malaise, possibly culminating in shock (see section 4.4).	
Nervous system disorders		Headache, dizzy sensations, paraesthesia	
Ear and labyrinth disorders		Tinnitus	
Cardiac disorders			Kounis syndrome
Gastro-intestinal disorders	Diarrhoea, nausea, vomiting, abdominal pains	Flatulence, diarrhoea may sometimes be a symptom of enterocolitis, which may, in some cases, be accompanied by blood in stools. A particular form of enterocolitis that can occur with antibiotics is pseudomembranous colitis (in most cases due to *Clostridium*	

		difficile) (see section 4.4).	
Hepatobiliary disorders		Elevated aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase, hepatitis, cholestasis	
Skin and subcutaneous tissue disorders		Cutaneous eruptions, rash, pruritus, urticaria and purpura. Cases of bullous eruptions (erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal necrolysis) have been reported.	Linear IgA disease
Renal and urinary disorders		Increase in blood urea and creatinine	
General disorders and administration site conditions		Asthenia	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

4.9 Overdose

Symptoms

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

Treatment

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class

A 20.1.1 Broad and medium spectrum antibiotics

Mechanism of action

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.

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.

5.2 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

After oral administration of a single dose of 100 mg of cefpodoxime, the maximum plasma concentration (C_{max}) obtained is 1 to 1,2 mg/l, and after administration of a dose of 200 mg of cefpodoxime, the maximum plasma concentration (C_{max}) obtained is 2,2 to 2,5 mg/l. In both cases, the time (T_{max}) taken to reach the maximum concentration is 2 to 3 hours.

Following administration of 100 and 200 mg twice daily for 14,5 days, the pharmacokinetic parameters of cefpodoxime remain unchanged, indicating that there is no accumulation of the active principle.
About 40 % of cefpodoxime is bound to plasma proteins, mainly albumin. This binding is principally to albumin and is of the non-saturable type.

Diffusion in fluids and tissues
Cefpodoxime proxetil diffuses well in lung parenchyma, bronchial mucosa, pleural fluid and tonsils.

Metabolism and Elimination
The main metabolite is cefpodoxime, resulting from the hydrolysis of cefpodoxime proxetil.
The elimination half-life of cefpodoxime is 2,4 hours. 80 % of cefpodoxime is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose calcium
Hydroxypropyl methylcellulose
Lactose monohydrate
Low substituted hydroxypropyl cellulose
Magnesium stearate
Sodium lauryl sulphate
Titanium Dioxide (C.I. No. 77891)
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, protected from light and moisture.
Keep in original packaging until required for use.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBERS

CEFPODOXIME 100 ADCO: 42/20.1.1/0388
CEFPODOXIME 200 ADCO: 42/20.1.1/0389

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 December 2012

10. DATE OF REVISION OF THE TEXT

17 November 2025

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