PROFESSIONAL INFORMATION

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

SANDOZ CEFPODOXIME 100 (Film-coated tablets)

SANDOZ CEFPODOXIME 40 mg/ 5 mL (Powder for suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

SANDOZ CEFPODOXIME 100 film-coated tablets: Each film coated tablet contains: cefpodoxime proxetil equivalent to 100 mg of cefpodoxime.

Each SANDOZ CEFPODOXIME 100 film coated tablet contains sugar (23,800 mg lactose monohydrate per tablet).

SANDOZ CEFPODOXIME 40 mg/5 mL suspension: Each 5 mL of suspension contains cefpodoxime proxetil equivalent to 40 mg of cefpodoxime.

Preservative: Sodium benzoate 0,5 % *m/m*.

Each 5 mL of SANDOZ CEFPODOXIME 40 mg/5 mL suspension contains sugar (1848,58 mg sucrose).

Each 5 mL of SANDOZ CEFPODOXIME 40 mg/5 ml suspension contains artificial sweetener (25 mg aspartame).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets and Powder for suspension.

SANDOZ CEFPODOXIME 100 film-coated tablets: White yellowish round film-coated tablets with a diameter of approx. 9 mm.

SANDOZ CEFPODOXIME 40 mg/5 ml suspension: Cream tinged to orange-yellow powder for reconstitution. The reconstituted suspension is orange-yellow in colour and has a slightly fruity odour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Adults:

SANDOZ CEFPODOXIME 100 film-coated tablets are indicated for short-term treatment of upper and lower respiratory tract infections due to susceptible microorganisms:

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

Use in children:

SANDOZ CEFPODOXIME 40 mg/ 5 mL suspension is indicated for short-term treatment of infections due to susceptible microorganisms:

Upper and lower respiratory tract infections:

- Otitis media
- Tonsillitis and pharyngitis
- Pneumonia

4.2. Posology and method of administration

Tonsillitis, pharyngitis and acute bronchitis

One tablet (100 mg) 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 tablets (200 mg) 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 (50 mg) tablet daily
– < 10 mL /minute	½ (50 mg) tablet every second day

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

In 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.

The following table may be used as a dosage guide:

Weight (kg)	***Dose***
Between 10 and 15 kg	5 mL (40 mg) every 12 hours
≥ 15 kg	10 mL (80 mg) every 12 hours

There is insufficient experience with SANDOZ CEFPODOXIME 40 mg/5 mL to make dosage recommendations for children less than 1 year of age.

4.3. Contraindications

- Hypersensitivity to cephalosporin antibiotics (see section 4.4).
- SANDOZ CEFPODOXIME 40 mg/5 mL must not be given to children with phenylketonuria, since the formulation contains aspartame (25 mg/5 mL).
- Children below 1 year of age (see section 4.2).

4.4 Special warnings and precautions for use

Hypersensitivity reactions:

Before initiating therapy with SANDOZ CEFPODOXIME 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 SANDOZ CEFPODOXIME. If an allergic reaction occurs, SANDOZ CEFPODOXIME should be discontinued.

Renal impairment:

SANDOZ CEFPODOXIME should be used with care in patients with renal impairment.

In patients with severe renal failure, it may be necessary to adjust the daily dose based on creatinine clearance (see section 4.2).

Changes in renal function have been observed with antibiotics of the same class and particularly when given concurrently with potentially nephrotoxic medicines such as aminoglycosides and/or potent diuretics. In such cases renal function should be monitored.

Gastrointestinal disease:

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

***Clostridium difficile* – associated disease:**

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. SANDOZ CEFPODOXIME should be discontinued if symptoms suggestive of pseudomembranous enterocolitis arise and appropriate antibiotic therapy should be initiated.

Interactions with laboratory tests:

Positive Coombs' test:

SANDOZ CEFPODOXIME may be absorbed onto the surface of red cell membranes and react with antibiotics directed against the medicine. This can produce a positive antiglobulin (Coombs') test and haemolytic anaemia.

Jaffè method interference:

SANDOZ CEFPODOXIME may interfere with Jaffè method of measuring creatinine concentrations and may produce falsely high values.

Information about some of the excipients of SANDOZ CEFPODOXIME

SANDOZ CEFPODOXIME contains sugar, which may have an effect on the glycaemic control of patients with diabetes mellitus.

SANDOZ CEFPODOXIME 100 contains lactose monohydrate. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take SANDOZ CEFPODOXIME 100.

SANDOZ CEFPODOXIME 40 mg/5 mL contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose- galactose mal-absorption or sucrase-isomaltase insufficiency should not take SANDOZ CEFPODOXIME 40 mg/5 mL.

SANDOZ CEFPODOXIME 40 mg/5 mL contains artificial sweetener (aspartame 25 mg/5 mL). Caution is advised in patients with phenylketonuria.

Superinfections:

The use of cefpodoxime, 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).

Encephalopathy

Beta-lactam antibiotics, including cefpodoxime (as in SANDOZ CEFPODOXIME), predispose patients to encephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), particularly if they have had an overdose or if they have impaired renal function.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported with unknown frequency in association with cefpodoxime treatment.
Patients should be advised of the signs and symptoms and monitored closely for skin reactions.
If signs and symptoms suggestive of these reactions appear, cefpodoxime should be withdrawn immediately, and an alternative treatment considered.
If the patient has developed a serious reaction such as SJS, TEN, DRESS or AGEP with the use of cefpodoxime, treatment with cefpodoxime must not be restarted in this patient at any time.

4.5 Interaction with other medicines and other forms of interaction

- Absorption of SANDOZ CEFPODOXIME is decreased by concurrent ingestion of antacids or histamine H2-receptor antagonists such as ranitidine.

  Therefore, mineral antacids (aluminium hydroxide, sodium bicarbonate) and histamine blocking H_2 blockers, which cause an increase in gastric pH, should be taken 2 or 3 hours after SANDOZ CEFPODOXIME administration. In contrast, a decrease in gastric pH (pentagastrin) will increase bioavailability.
- Probenecid reduces the renal excretion of SANDOZ CEFPODOXIME and increases serum levels thereof.
- The bioavailability increases if SANDOZ CEFPODOXIME is administered during meals (acid pH).
- Enhanced nephrotoxicity with a loop diuretic (e.g. furosemide) may occur.
- Changes in renal function have been observed with antibiotics of the same class, particularly when given concurrently with potentially nephrotoxic medicines such as aminoglycosides (e.g. gentamicin) and/or potent diuretics. In such cases, renal function should be monitored (see section 4.2).
- As with other cephalosporins, isolated cases showing development of a positive Coombs test

have been reported (see section 4.4).

- In patients treated with SANDOZ CEFPODOXIME, a false positive reaction for glucose in the urine may occur with Benedicts or Fehlings solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.
- Concurrent use with anticoagulants, such as warfarin, may increase the risk of bleeding.

Special INR imbalance issues

Numerous cases of increased oral anticoagulant activity have been reported in patients receiving antibiotics. The severity of the infection or inflammation, age and general health status of the patient appear to be risk factors. Under these circumstances, it seems difficult to determine to what extent the infection itself or its treatment play a role in the INR imbalance. However, certain classes of antibiotics are more involved, particularly fluoroquinolones, macrolides, cyclines, cotrimoxazole and certain cephalosporins.

4.6 Fertility, pregnancy and lactation

Safety and efficacy have not been established in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Dizziness has been reported during treatment with cefpodoxime and may affect patients' ability to drive or operate machinery.

4.8 Undesirable effects

The following side effects have been reported:

Infections and Infestations

Frequent: Oral and vaginal candidiasis, superinfections, overgrowth of non-susceptible organisms

Blood and lymphatic system disorders

Frequent: Thrombocytosis, leucopenia and eosinophilia, reduction of haemoglobin.

Less frequent: Thrombocytopenia, neutropenia, agranulocytosis, haemolytic anaemia, hypoprothrombinaemia, aplastic anaemia, pancytopenia, lymphocytosis, anaemia, leucocytosis, lymphocytosis, leukocytosis.

Immune system disorders

Less frequent: Hypersensitivity reactions, anaphylactic reactions, angioedema, bronchospasm, malaise, shock

Metabolism and nutrition disorders

Frequent: Appetite loss

Nervous system disorders

Frequent: Headache

Less frequent: Asthenia, seizures, CNS toxicity, dizzy sensations, paraesthesia

Ear and labyrinth disorders

Less frequent: Tinnitus, hearing loss

Gastrointestinal disorders:

Frequent: Nausea, vomiting, flatulence, abdominal pains and diarrhoea

Less frequent: Dyspepsia, pseudomembranous colitis, blood in stools, acute pancreatitis, fever

Hepatobiliary disorders:

Less frequent: Hepatic dysfunction including cholestasis, elevated liver enzymes (elevations of aspartate transaminase (AST), alanine transaminase (ALT) and alkaline phosphatase), bilirubinaemia, liver injury, hepatitis, cholestatic jaundice

Skin and subcutaneous tissue disorders

Frequent: Skin rashes, urticaria, pruritus, purpura, reactions resembling serum sickness, cutaneous eruptions. Cases of bullous eruptions have been reported

Less frequent: Erythema multiforme or Stevens-Johnson syndrome, toxic epidermal necrolysis

Frequency unknown: Acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)

Renal and urinary disorders:

Less frequent: Increase in blood urea and creatinine, renal dysfunction, toxic nephropathy

General disorders and administrative site conditions

Less frequent: Fatigue

Investigations:

Less frequent: A positive Coombs test may occur

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 reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Suspected adverse reactions can also be reported directly to the HCR via https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

4.9 Overdose

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 is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological classification: A 20.1.1 Broad and medium spectrum antibiotics

Pharmacotherapeutic group: Antibacterials for systemic use, ATC code: J01DA33

5.1 Pharmacodynamic properties

Cefpodoxime proxetil is the prodrug of the bactericidal antibiotic cefpodoxime. Cefpodoxime is a semisynthetic β-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*, β-lactamase and non β-lactamase producing strains
- *Haemophilus para-influenzae*, β-lactamase and non β-lactamase producing strains
- *Moraxella catarrhalis (Branhamella catarrhalis)*, β-lactamase and non β-lactamase producing strains
- *Neisseria gonorrhoeae*, β-lactamase and non β-lactamase 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.

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:

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. 80 % of cefpodoxime is excreted unchanged in the urine.

6. Pharmaceutical particulars

6.1 List of excipients

SANDOZ CEFPODOXIME 100 film-coated tablets:

Carboxymethylcellulose calcium, crospovidone (Kollidon CL), hydroxypropylcellulose (Klucel LF), hypromellose (Methocel E 5), lactose monohydrate, magnesium stearate, sodium lauryl sulphate (Texapon K12), talc, titanium dioxide (C.I. 77891).

SANDOZ CEFPODOXIME 40 mg/5 ml suspension:

Aspartame, citric acid anhydrous, guar galactomannan, lemon flavouring, orange flavouring, silicon dioxide, sodium benzoate, sodium chloride, sorbitan trioleate, sucrose, talc, ferric oxide (E172).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Tablets: 24 months

Powder for suspension: 36 months

6.4 Special precautions for storage

SANDOZ CEFPODOXIME 100 film-coated tablets:

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

Store in the original packaging.

SANDOZ CEFPODOXIME 40 mg/5 mL suspension:

Before reconstitution: Store at or below 25 °C. Keep container tightly closed. Protect from light

After reconstitution: Shake the bottle before use. Use within 14 days. Discard any unused portion. Store in a refrigerator (2 to 8°C).

6.5 Nature and contents of container

SANDOZ CEFPODOXIME 100 film-coated tablets: PVC/PVDC/aluminium foil or Aluminium foil with PE backing blister pack of 10 tablets.

SANDOZ CEFPODOXIME 40 mg/ 5 mL: 60 mL or 100 mL amber glass bottle with polypropylene white screw cap containing powder for reconstitution up to 50 mL or 100 mL of suspension. The bottle is packed in a carton.

Not all packs and pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Directions for preparation of suspension:

1. Before preparing the suspension, remove and dispose of the desiccant contained in a capsule inside the bottle cap.
2. Add 37 mL water for the 50 mL pack and 74 mL water for the 100 mL pack. Replace the cap.
3. Shake thoroughly to obtain an evenly dispersed suspension.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

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Sandoz SA Customer Call Centre 0861 726 225 (SANCAL)

8. REGISTRATION NUMBERS

SANDOZ CEFPODOXIME 100: A39/20.1.1/0398

SANDOZ CEFPODOXIME 40 mg/5 mL: A39/20.1.1/0397

9. DATE OF FIRST AUTHORISATION

SANDOZ CEFPODOXIME 100: 08 February 2008

SANDOZ CEFPODOXIME 40 mg/5 mL: 15 August 2008

10. DATE OF REVISION OF THE TEXT

28 July 2025

[1]Company Reg. No.: 1990/001979/07