BANADOZ ® Film-coated tablet
CEFPODOXIME

COMPOSITION

Each film-coated tablet Banadoz® 100 mg contains: Cefpodoxime proxetil corresponding to 100 mg of cefpodoxime.

Each film-coated tablet Banadoz® 200 mg contains: Cefpodoxime proxetil corresponding to 200 mg of cefpodoxime.

DESCRIPTION :

Like other betalactam drugs, cefpodoxime exerts antibacterial activity by binding to and inhibiting the action of certain bacterial cell wall synthetic enzymes, namely the penicilin binding proteins. This results in the interuption of cell wall (peptodoglycan) biosynthesis, which loads to bacterial cell lysis and death.

After oral administration cefpodoxime proxetil is absorbed from the intestinal tract and is rapidly hydrolyzed by esterases in the intestinal wall to the antibacterially active.

The absorption of cefpodoxime proxetil is enhanced when given after meals. The duration of high serum levels result in effectiveness with twice daily administration.

INDICATION

For the treatmen of patients with infections caused by susceptible strains in the conditions listed below :

1. Lower respitory tract
   Acute, communily-acquired pneumonia caused by *S.pneumoniae, H.influenzae* (non-betalactamase producing strains only).
2. Sexually transmitted disease.
   Acute, uncomplicated urethral and cervical gonorrhea (including penicillinase strains).
   Note :
   - The efficacy of cefpodoxime in treating male patients with rectal infection caused by *N.gonorrhea* has not been established.
   - Data do not support the use of cefpodaxime proxetil in treatment of pharyngeal infections due to *N.gonorrhea* in man or women.
3. Skin and Skin structures
   Uncomplicated skin and skin structures infections caused by *Staphylococcus aerus* (including penicillinase producing strains) or *Streptococcus pragenies*, (abscesses should be surgically drained as clinically indicated).
4. Acute otitis media caused by *S.pneumoniae, H.influenzae* (including beta-lactamase producing strains) or *Moroxella (Bramhanella) catarrhalis*, pharyngitis and/or tonsillitis caused by *S.pyogenes.*
5. Urinary tract
   Uncomplicated urinary tract infections (cystitis) caused by *E.coli, Klebsiella pneumoniae, Proteus mirabilis,* or *Staphylococcus soprophyticus*

CONTRA INDICATIONS

Hypersensitivy to cefpodoxime, to any of the cephem-lypo-antibiotics or any excipients of the tablet.

SPECIAL WARNING AND PRECAUTIONS

Cefpodoxime proxetil should be given with caution to:

- Patients with poor oral ingestion, patients with unclear parenteral alimentation, elderly poeple, and patients with poor general conditions (these patients should be carefully observed for symptoms of deficiency in vitamin K).
- Patients with severe kidney disorders.
- Patients or their parents or siblings who are constitutionally predisposed to alergic reactions, such as bronchial asthma, eruption and urticaria

Safety for use in children has not been established.

Before therapy with cefpodoxime is institude, careful inquiry should be made to determine whether the patient has had any previous hypersensitivity reactions to cefpodoxime, cephems (cephalosporin and cephamycin), penicillins, or other beta-lactam drugs.

Cefpodoxime is contraindicated in patients who have had a previous hypersensitivity reaction to any cephalosporin.

It is also contraindicated in patients who have had a previous immediate and/or any severe hypersensitivity reaction to any penicillin or any other beta-lactam drug.

Cefpodoxime should be given with caution to patients who have had any other type of hypersensitivity reaction to a penicillin or any other beta-lactam drug.

Antibiotic associated diarrhoea, colitis and pseudomembranous colitis have been reported with the use of cefpodoxime. These diagnoses should be considered in any patient who develops diarrhoea during or shortly after treatment. Cefpodoxime should be discontinued if severe and/or bloody diarrhoea occurs during treatment and appropriate therapy instituted.

Cefpodoxime should always be used with caution in patiens with a history of gastrointestinal disease, particularly colitis.

As with all beta-lactam antibiotics neutropenia and more rarely agranulocylosis may develop particularly during extended treatment. For cases of treatment lasting longer than 10 days, the blood count should be monitared and treatment discontinued if neutropenia is found.

Cephems may be absorbed onto the surface of red cell membranes and react with antibodies directed against the drug. This can produce a positive Coomb's test and very rarely, haemolytic anaemia. Cross-reactivity may occur with penicillin for this reaction.

Changes in renal function have been absorved with cephalosporin antibiotics, particulary when given cancurrently with potientially nephrotoxic drugs such as aminoglycosides and/or patential diuretics. In such cases renal function should be monitored.

As with other antibiotics, the prolonged use of cefpodoxime proxetil may result in the overgrowth of non-susceptible organisms.

This medicinal products contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency of glucose-galactose malabsorption should not take this medicine.

Pregnancy and Lactation

For cefpodoxime proxetil, no clinical data an exposed pregnancies are available.
Caution should be exercised when prescribing to pregnant women.

Cefpodoxime is excreted in human milk. Mothers should stop breastfeeding during treatment with cefpodoxime.

SIDE EFFECTS :

Shock

Shocks symptoms may occur rarely, therefore, patients should be carefully observed. Should any such symptoms as discomfort oral cavity discomfort, dizziness, and inclination for stool, tinnitus and perspiration appear, the drug should be discontinued.

Hypersensitivity

Should any such symptoms of hypersensitivity as eruption, urticaria, erythema, pruritus, fever, lymphadenopathy and arthralgia, occurance of cutaneous muco-ocular syndrome (Steven-Johnson Syndrome) and 1999 necrolysis epidermal toxic lyell type (lyell syndrome) appear, the drug should be discontinued and appropriate therapy instituted.

Haematologic

Eosinophilia and thrombocytopenia may occur occasionally and granulocylopenia rarely, pancylopenia, decreased haemoglobin and haematocrit. In this connection, accurance of haemolytic anemia has been reported after use of other antibiotic of the Cephem type C.Hematologic.

Hepatic

Abnormalities in hepatic function tests such as elevation in SGOT, SGPT, alkaline phosphatase and LDH may occur occasionally.

Renal

BUN and blood creatinine may be increased occasionally since a serious renal function disorder such acute renal insufficiency may occur rarely after administration of Cephems antibiotic agents, careful observation and periodic examinations should be made. If any abnormality is observed, adminstration should be discontinued and the patients should receive appropriate treatment.

Gastro Intestinal

Rarely, a serious form of colitis accompanied with bloodystools, such as pseudomembranous colitis, may occur. If abdominal pain or frequent diarrhea occurs, administration should be discontinued immediately and appropriate treatment should be initiated. Diarrhea, loose stools, stomach pain, abdominal pain, anorexia, and gastric discomfort may occur infrequently and rarely constipation may occur.

Super infection

Stomatilis or candidiasis may occur rarely.

Avitaminosis

Vitamin K deficient symptoms (e.g.hypoprothrombenemia, hemorrhagic tendency) and vitamin B deficient symptoms (e.g.glossitis, stomatitis, anorexia, neuritis) may occur rarely.

DRUG INTERACTIONS

Antacid

Concomitant administration of high doses of antacids (sodium bicarbonate and alumunium

hydroxide) or H2 blockers reduces peak levels by to 24% to 42% and the extent of absorption by 27% to 32% respectively.

Probenecids

Ronal excretion of cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC and 20% increase in peak cefpodoxime plasma levels.

Nephrotoxic drugs

Although nephrotoxicity has not been noted when cefpodoxime proxetil was given alone, close monitoring of renal function is advised when cefpodoxime proxetil is administered concomitantly with nephrotoxic drugs.

DOSAGE AND METHOD OF ADMINISTRATION

Posology

Cefpodoxime proxetil should be administered orally after meals.

Type of Infections	Total daily dosage	Dose frequency	Durations
Acute community acquired pneumoniae	400 mg	200 mg every 12 hours	14 days
Uncomplicated gonorhoea (men or women) and rectal gonococcal infections (women)	200 mg	Single dose	
Skin and skin structure	800 mg	400 mg every 12 hours	14 days
Pharyngitis and/or tonsilitis	200 mg	100 mg every 12 hours	10 days
Uncomplicated urinary tract infaction	200 mg	100 mg every 12 hours	7 days

Method of administration

For oral administration

The tablets should be taken with food for optimum absorption.

Overdose

In the event of overdose with cefpodoxime proxetil, supportive and symtomatic therapy is indicated. In cases of overdose, particularly in patients with renal insufficiency, encephalopathy may occur. The encephalopathy is usually reversible once cefpodoxime plasma levels have fallen.

Presentation

Banadoz® 100 mg
Box, 3 blisters @ 10 film-coated tablets
Reg. No : DKI0980302417A1

Banadoz® 200 mg
Box, 3 blisters @ 10 film-coated tablets
Reg. No. : DKI0980302417B1

ON DOCTOR'S PRESCRIPTION ONLY

HARUS DENGAN RESEP DOKTER

Store in the original package.
Do not store above 25°C

Manufactured by
Sandoz GmbH
Biochemiestraβe 10
A-6250 Kundl, Austria

Imported by
PT.Sandoz Indonesia
Jakarta-Indonesia