240mm

165mm

pharmaniaga®

Xylid

cefuroxime 125 mg

Tablet

DESCRIPTION
White, oblong tablet, plain on both sides.

COMPOSITION
Each tablet contains cefuroxime 125mg
(as cefuroxime axetil).

PHARMACODYNAMICS
The prevalence of acquired resistance is geographically and time dependent and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

***In vitro* susceptibility of micro-organisms to cefuroxime**
Commonly Susceptible Species
Gram-Positive Aerobes:
Staphylococcus aureus (methicillin susceptible)
Coagulase negative staphylococcus (methicillin susceptible)
Streptococcus pyogenes
Beta-hemolytic streotococci
Gram-Negative Aerobes:
Haemophilus influenzae including ampicillin resistant strains
Haemophilus parainfluenzae
Moraxella catarrhalis
Neisseria gonorrhoea including penicillinase and non-penicillinase producing
strains
Gram-Positive Anaerobes:
Peptostreptococcus spp.
Propionibacterium spp.
Spirochetes:
Borrelia burgdorferi
Organisms for which acquired resistance may be a problem
Gram-Positive Aerobes:
Streptococcus pneumoniae
Gram-Negative Anerobes:
Citrobacter spp. not including *C. freundii*
Enterobacter spp. not including *E. aerogenes* and *E. cloacae*
Escherichia coli
Klebsiella spp. including *Klebsiella pneumoniae*
Proteus mirabilis
Proteus spp. not including *P. penneri* and *P. vulgaris*
Providencia spp.
Gram-Positive Anaerobes:
Clostridium spp. not includin *C. difficile*
Gram-Negative Anaerobes:
Bacteroides spp. not including *B. fragilis*
Fusobacterium spp.
Inherently resistant organisms
Gram-Positive Aerobes:
Enterococcus spp. including *E. faecalis* and *E. faecium*
Listeria monocytogenes
Gram-Negative Aerobes:
Acinetobacter spp.
Burkholderia cepacia
Campylobacter spp.
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Morganella morgani
Proteus penneri
Proteus vulgaris
Pseudomonas spp. including *Pseudomonas aeruginosa*
Serratia spp.
Stenotrophomonas maltophilia
Gram-Positive Anaerobes:
Clostridium difficile
Gram-Negative Anaerobes:
Bacteroides fragilis
Others:
Chlamydia species
Mycoplasma species
Legionella species

PHARMACOKINETICS
After oral administration, cefuroxime is slowly absorbed from the gastrointestinal tract and rapidly hydrolysed in the intestinal mucosa and blood to release cefuroxime into the circulation. Optimum absorption occurs when it is administered shortly after a meal.

Following administration of cefuroxime tablets peak serum levels (2.1 mg/L for a 125 mg dose, 4.1 mg/L for a 250 mg dose, 7.0 mg/L for a 500 mg dose and 13.6 mg/L for a 1 g dose) occur approximately 2 to 3 hours after dosing when taken with food.

The absorption of cefuroxime from the suspension is more prolonged compared with tablets, leading to later, lower peak serum levels and slightly reduced systemic bioavailability (4 - 17 % less). Post peak levels , the serum half - life is between 1 and 1.5 hours. Protein binding has been variously stated as 33 - 50 % depending on the methodology used.

Cefuroxime is not metabolised and is excreted by glomerular filtration and tubular secretion.

Concurrent administration of probenecid increases the area under the mean serum concentrations time curve by 50%.

Cefuroxime is excreted unchanged, by glomerular filtration and renal tubular secretion, and high concentrations are achieved in the urine. Concurrent administration of probenecid increases the area under the mean serum concentrations time curve by 50%. Probenecid competes for renal tubular secretion with cefuroxime resulting in higher and more prolonged plasma concentrations of cefuroxime. Small amounts of cefuroxime are excreted in bile. Plasma concentration is reduced by dialysis.

INDICATIONS
Cefuroxime is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms.
It is indicated for the treatment of infections caused by susceptible bacteria. Susceptibility to cefuroxime will vary with geography and time and local susceptibility data should be consulted where available (*See Pharmacological properties, Pharmacodynamics*).

Indications include:
- upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis
- lower respiratory tract infections for example, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis
- genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis
- skin and soft tissue infections for example, furunculosis, pyoderma and impetigo
- gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis

Cefuroxime is also available as the sodium salt for parenteral administration. This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated.
Where appropriate cefuroxime is effective when used following initial parenteral cefuroxime sodium in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

CONTRAINDICATIONS
Cefuroxime is contraindicated to those who is:
- patients with known hypersensitivity to cephalosporin antibiotics;
- hypersensitivity to cefuroxime; or
- have history of severe hypersensitivity (e.g anaphylactic reaction) to any other type of beta lactam antibacterial agent (penicillins, monobactams and carbapenems).

WARNINGS AND PRECAUTIONS
Hypersensitviity
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta - lactams. Before initiating therapy with cefuroxime, careful inquiry should be made concerning previous hypersensitivity reaction to penicillins, cephalosporins, carbapenems or other beta lactam agents. If an allergic reaction occurs, cefuroxime must be discontinued immediately and appropriate alternative therapy instituted.

Overgrowth of non - susceptible organisms
As with other antibiotics, use of cefuroxime may result in the overgrowth of *Candida*. Prolonged use of cefuroxime may result in the overgrowth of non susceptible organisms (e.g., enterococci, *Clostridium difficile*), which may require interruption of treatment.

Pseudomembranous colitis
Pseudomembranous colitis has been reported with the use of antibiotics, and may range in severity from mild to life threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patients investigated further.

Kidney function
Although cefuroxime rarely produces alterations in kidney function, evaluation of renal status during therapy is recommended, especially in seriously ill patients receiving the maximum doses.

The total daily doses of cefuroxime should be reduced in patients with transient or persistent renal insufficiency because high and prolonged serum antibiotic concentrations can occur in such individuals from usual doses.

attn	customer **Pharmaniaga Manufacturing Berhad**	date **28.10.2022**
1 colours **Black**		**Please Chop & Sign For Approval**
size (L)**240 x** (W)**165mm** description **Xylid 125mg - Front**	material **60gm simili**	
FocusPrint SDN BHD	t: 603-8766 6030 f: 603-8766 6033 (Factory) website: www.focusprint.com.my	
artwork prepared by: cynthia yap	email: graphic@focusprint.info (Graphic Dept)	**date:**

IMPORTANT ! **Please note that this colour print is for visual purpose only. Output colour might differ in actual production.**

ARTWORK LOG

Revision no.	Date	Reason for Change
01	21.09.2020	- New artwork created.
02	25.09.2020	- Amend wording.
03	20.10.2022	- Amend wording and date of revision.
04	28.10.2022	- Amend wording, move date of revision and delect PRP no.
05	28.10.2022	- Update Date of revision.

240mm

165mm

Nephrotoxicity has been reported following concomitant administration of aminoglycoside antibiotics and cephalosporins.

Therapy
With a sequential therapy regimen, the timing of change to oral therapy is determined by severity of the infection, clinical status of the patient and susceptibility of the pathogens involved. If there is no clinical improvement within 72 hours, the parenteral course of treatment must be continued.

Effects on the Ability to Drive or Operate Machinery
As this medicine may cause dizziness, patients should be warned to be cautious when driving or operating a machinery.

Pregnancy
There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime but, as with all drugs, it should be administered with caution during the early months of pregnancy.

Lactation
Since cefuroxime is excreted in human milk, caution should be exercised when cefuroxime is administered to a nursing woman.

Paediatric Use
There is no experience of using cefuroxime in children less than 3 months.

DRUG INTERACTION
Drugs which reduce gastric acidity may result in a lower bioavailability of cefuroxime compared with that of the fasting state and tend to cancel the effect of enhances postprandial absorption.

In common with other antibiotics, cefuroxime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

As a false-negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/ plasma glucose levels in patients receiving cefuroxime. This antibiotic does not interfere in the alkaline picrate assay for creatinine. False-positive result also may occur in the Coomb's test.

Concomitant administration of probenecid with cefuroxime increase plasma concentration by reducing the renal clearance of cefuroxime.

ADVERSE REACTIONS
Adverse drug reactions to cefuroxime are generally mild and transient in nature.

Infections and Infestations
Common: Overgrowth of Candida

Blood and Lymphatic System Disorders
Common: Eosinophilia
Uncommon: Positive Coomb's test, thrombocytopenia and leukopenia (sometimes profound; sore throat can be a sign of lack of white blood cells).
Very rare: Haemolytic anaemia

Cephalosporins as a class tend to be absorbed onto the surface of red cells membranes and react with antibodies directed against the drug to produce a positive Coomb's test (which can interfere with cross - matching of blood) and very rarely haemolytic anaemia.

Immune System Disorders (including hypersensitivity reactions)
Uncommon: Skin rashes
Rare: Urticaria and pruritus
Very rare: Drug fever, serum sickness and anaphylaxis

Nervous System Disorders
Common: Headache and dizziness

Gastrointestinal Disorders
Common: Gastrointestinal disturbances including diarrhoea, nausea and abdominal pain
Uncommon: Vomiting
Rare: Pseudomembranous colitis

Hepatobiliary Disorders
Common: Transient increase of hepatic enzyme levels, [alanine transaminase (ALT) serum glutamic-pyruvic transaminase (SGPT); aspartate transaminase (AST) serum glutamic-oxaloacetic transaminase (SGOT), lactate dehydrogenase (LDH)]
Very rare: Jaundice (predominantly cholestatic) and hepatitis

Skin and Subcutaneous Tissue Disorders
Very rare: Erythema multiforme, Steven - Johnson syndrome and toxic epidermal necrolysis (exanthematic necrolysis).

DOSAGE AND ADMINISTRATION
The usual course of therapy is seven days (range 5 to 10 days).
Cefuroxime should be taken after food for optimum absorption.

• Adults	
Most infections	250 mg twice daily
Urinary tract infections	250 mg twice daily
Mild to moderate lower respiratory tract infections e.g. bronchitis	250 mg twice daily
More severe lower respiratory tract infections, or if pneumonia is suspected	500 mg twice daily
Pyelonephritis	250 mg twice daily
Uncomplicated gonorrhoea	single dose of 1 g

Sequential therapy
Pneumonia
1.5 g cefuroxime sodium twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily cefuroxime axetil oral therapy for 7 to 10 days.
Acute exacerbations of chronic bronchitis
750 mg cefuroxime sodium twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily cefuroxime axetil oral therapy for 5 to 10 days.

Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.

• Children	
Most infections	125 mg (1 x 125 mg tablet) twice daily
Children with otitis media or, where appropriate, with more severe infections	250 mg (1 x 250 mg tablet or 2 x 125 mg tablets) twice daily

Cefuroxime tablets should not be crushed or split and are therefore unsuitable for treatment of patients, such as younger children, who cannot swallow whole tablets.
There is no experience of using cefuroxime in children under the age of 3 months.

• Renal impairment

Cefuroxime is primarily excreted by kidneys. In patients with markedly impaired renal function it is recommended that the dosage of cefuroxime be reduced to compensate for its slower excretion (see the table below).

Creatinine Clearance	T 1/2 (hours)	Recommended Dosage
≥30 ml/min	1.4 - 2.4	No dose adjustment necessary standard dose of 125 mg to 500 mg given twice daily
10-29 ml/min	4.6	Standard individual dose given every 24 hours
<10 ml/min	16.8	Standard individual dose given every 48 hours
During haemodialysis	2 – 4	standard individual dose should be given at the end of each dialysis

Hepatic impairment:
There are no data available for patients with hepatic impairment. Since cefuroxime is primarily eliminated by the kidney, the presence if hepatic dysfunction is expected to have no effect on the pharmacokinetics of cefuroxime.

Method of administration
Oral use

OVERDOSAGE
Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

ROUTE OF ADMINISTRATION
Oral

STORAGE CONDITION
Store below 30°C.
Protect from light.

SHELF - LIFE
Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION
Pack of 10 and 50 tablets in strips or blisters.

Date of revision: 17/03/2023

PRODUCT REGISTRATION HOLDER/ MANUFACTURER:
PHARMANIAGA MANUFACTURING BERHAD (198001006232)
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

attn	customer Pharmaniaga Manufacturing Berhad	date 28.10.2022
1 colours Black		Please Chop & Sign F or Approval
size (L) 240 x (W)165mm description Xylid 125mg - Back	material 60gm simili	
FocusPrint SDN BHD	t: 603-8766 6030 f: 603-8766 6033 (Factory) website: www.focusprint.com.my	
artwork prepared by: cynthia yap	email: graphic@focusprint.info (Graphic Dept)	date:

IMPORTANT ! Please note that this colour print is f or visual purpose only . Output colour might differ in actual pr oduction.

ARTWORK LOG

Revision no.	Date	Reason for Change
01	21.09.2020	- New artwork created.
02	25.09.2020	- Amend wording.
03	20.10.2022	- Amend wording and date of revision.
04	28.10.2022	- Amend wording, move date of revision and delect PRP no.
05	28.10.2022	- Update Date of revision.