VITAMED
REKAH GROUP
Pharmaceutical Industries LTD

אוקטובר 2023

עדכון העלון לרופא של התכשיר: Cefuroxime- Vit,
Powder for solution or suspension for injection or infusion

צוות רפואי נכבד,

חברת ויטאמד תעשיות פרמצבטיות בע"מ, מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:
צפורוקסים – ויט.
בהודעה זו מפורטים העדכונים המהווים החמרה במידע בטיחותי בלבד למידע מלא יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות. ניתן לעיין בכתובת:
https://israeldrugs.health.gov.il

כמו כן, ניתן לקבלו מודפס ע"י פנייה לבעל הרישום:

ויטאמד תעשיות פרמצבטיות בע"מ, רח' הטחנה 6, ת.ד. 114, בנימינה 3055002, ישראל.

הרכב התכשיר:

Each vial contains Cefuroxime (as Sodium) 750 mg.

התוויה מאושרת:

Cefuroxime-Vit is indicated for the treatment of the infections listed below in adults and children, including neonates (from birth):

- Community acquired pneumonia
- Acute exacerbations of chronic bronchitis
- Complicated urinary tract infections, including pyelonephritis
- Soft-tissue infections: cellulitis, erysipelas and wound infections
- Intra-abdominal infections
- Prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynaecological surgery (including caesarean section)
- Nose infections for example, sinusitis
- Septic arthritis

העלון לרופא עודכן באוקטובר 2023. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים בצהוב):

[...]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 750 mg of cefuroxime (as 789 mg cefuroxime sodium).

Excipients with known effects:
Each vial contains approximately 42 mg sodium (1.8 mmol).

For a full list of excipients, see section 6.1.

[...]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefuroxime – Vit is indicated for the treatment of the infections listed below in adults and children, including neonates (from birth):

- Community acquired pneumonia.
- Acute exacerbations of chronic bronchitis.
- Complicated urinary tract infections, including pyelonephritis.
- Soft-tissue infections: cellulitis, erysipelas and wound infections.
- Intra-abdominal infections.
- Prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynaecological surgery (including caesarean section).
- Nose infections for example, sinusitis.
- Septic arthritis.

In the treatment and prevention of infections in which it is very likely that anaerobic organisms will be encountered, cefuroxime should be administered with additional appropriate antibacterial agents.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Table 1. Adults and children ≥ 40 kg

Indication	**Dosage**
Community acquired pneumonia and acute exacerbations of chronic bronchitis	750 mg every 8 hours (intravenously or intramuscularly)
Soft-tissue infections: cellulitis, erysipelas and wound infections.	
Intra-abdominal infections	
Sinusitis, septic arthritis	750 mg every 8 hours (intravenously or intramuscularly). For more severe infections, this dose should be increased to 1.5 g every 8 hours i.v. The frequency of i.m. or i.v. injections can be increased to six-hourly if necessary, giving total doses of 3 g to 6 g daily. Where clinically indicated, some infections respond to 750 mg or 1.5 g twice daily (i.v. or i.m.)
Complicated urinary tract infections, including pyelonephritis	1.5 g every 8 hours (intravenously or intramuscularly)
Severe infections	750 mg every 6 hours (intravenously) 1.5 g every 8 hours (intravenously)
Surgical prophylaxis for gastrointestinal, gynaecological surgery (including caesarean section) and orthopaedic operations	1.5 g with the induction of anaesthesia. This may be supplemented with two 750 mg doses (intramuscularly) after 8 hours and 16 hours
Surgical prophylaxis for cardiovascular and oesophageal operations	1.5 g with induction of anaesthesia followed by 750 mg (intramuscularly) every 8 hours for a further 24 hours

Table 2. Children < 40 kg

	Infants and toddlers > 3 weeks and children < 40 kg	**Infants (birth to 3 weeks)**
Community acquired pneumonia	30 to 100 mg/kg/day (intravenously) given as 3 or 4 divided doses; a dose of 60 mg/kg/day is appropriate for most infections	30 to 100 mg/kg/day (intravenously) given as 2 or 3 divided doses (see section 5.2)
Complicated urinary tract infections, including pyelonephritis		
Soft-tissue infections: cellulitis, erysipelas and wound infections		
Intra-abdominal infections		
Sinusitis, septic arthritis	Doses of 30 to 100 mg/kg/day given as three or four divided doses. A dose of 60mg/kg/day is appropriate for most infections.	Doses of 30 to 100 mg/kg/day given as two or three divided doses.

Renal impairment

Cefuroxime is primarily excreted by the kidneys. Therefore, as with all such antibiotics, in patients with markedly impaired renal function it is recommended

that the dosage of Cefuroxime - Vit should be reduced to compensate for its slower excretion.

[...]

Method of administration
Cefuroxime – Vit should be administered by intravenous injection over a period of 3 to 5 minutes directly into a vein or via a drip tube or infusion over 30 to 60 minutes, or by deep intramuscular injection.

Intramuscular injections should be injected well within the bulk of a relatively large muscle and not more than 750 mg should be injected at one site. For doses greater than 1.5 g intravenous administration should be used.

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

[...]

4.4 Special warnings and precautions for use

[...]

Important information about

excipients 750 mg vial:
This medicinal product contains approximately 42 mg (1.8 mmol) sodium per vial, equivalent to 2.1% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

[...]

4.8 Undesirable effects

[...]

Treatment related adverse reactions, all grades, are listed below by MedDRA body system organ class, frequency and grade of severity. The following convention has been utilised for the classification of frequency: very common ≥1/10; common ≥ 1/100 to < 1/10; uncommon ≥ 1/1,000 to < 1/100; rare ≥ 1/10,000 to < 1/1,000; very rare < 1/10,000 and not known (cannot be estimated from the available data).

[...]

5. Pharmacological Properties

5.1 Pharmacodynamic properties

[...]

Microorganism	Breakpoints (mg/L)	
	Susceptible	Resistant
Enterobacteriaceae[1]	≤8[2]	>8
Staphylococcus spp.	Note[3]	Note[3]
Streptococcus A, B, C and G	Note[4]	Note[4]
Streptococcus pneumoniae	≤0.5	>1
Streptococcus (other)	≤0.5	>0.5
Haemophilus influenzae	≤1	>2
Moraxella catarrhalis	≤4	>8
Non-species related breakpoints[1]	≤4[5]	>8[5]

[1] The cephalosporin breakpoints for *Enterobacteriaceae* will detect all clinically important resistance mechanisms (including ESBL and plasmid mediated AmpC). Some strains that produce beta- lactamases are susceptible or intermediate to 3rd or 4th generation cephalosporins with these breakpoints and should be reported as found, i.e. the presence or absence of an ESBL does not in itself influence the categorization of susceptibility. In many areas, ESBL detection and characterization is recommended or mandatory for infection control purposes.
[2] Breakpoint relates to a dosage of 1.5 g × 3 and to *E. coli, P. mirabilis* and *Klebsiella* spp. only
[3] Susceptibility of staphylococci to cephalosporins is inferred from the methicillin susceptibility except for ceftazidme and cefixime and ceftibuten, which do not have breakpoints and should not be used for staphylococcal infections.
[4] The susceptibility of streptococcus groups A, B, C and G to cephalosporins is inferred from the benzylpenicillin susceptibility.
[5] Breakpoints apply to daily intravenous dose of 750 mg × 3 and a high dose of at least 1.5 g × 3.

[...]

6.3 Shelf life

Dry Powder
The expiry date of the product is indicated on the packaging materials.

[...]

6.6 Special precautions for disposal and other handling

[...]

Additional volumes and concentrations, which may be useful when fractional doses are required				
Vial size	Routes of administration	Physical State	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)* *
750 mg powder for solution for injection or infusion				
750 mg	intramuscular	suspension	3 mL	216
	intravenous bolus	solution	at least 6 mL	116
	intravenous infusion	solution	at least 6 mL*	116

* Reconstituted solution to be added to 50 or 100 mL of compatible infusion fluid (see information on compatibility, below)

[...]

בברכה,

חברת ויטאמד תעשיות פרמצבטיות בע"מ