VITAMED
REKAH GROUP
Pharmaceutical Industries LTD

נובמבר 2023

עדכון עלון לרופא של התכשיר:
Ceftazidime-Vit
Powder for solution for injection

צוות רפואי נכבד,

חברת ויטאמד תעשיות פרמצבטיות בע"מ, מבקשת להודיעכם על עדכון העלון לרופא של התכשיר: **צפטזידים-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 לקבלם מודפסים ע"י פנייה לבעל הרישום:

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

הרכב התכשיר:

Each vial contains 1 g ceftazidime (as 1.164 sterile ceftazidime pentahydrate).

התוויה מאושרת:

Ceftazidime-VIT is indicated for the treatment of the infections listed below in adults and children including
neonates (from birth).
•Nosocomial pneumonia
•Broncho-pulmonary infections in cystic fibrosis
•Bacterial meningitis
•Chronic suppurative otitis media
•Malignant otitis externa
•Complicated urinary tract infections
•Complicated skin and soft tissue infections
•Complicated intra-abdominal infections
•Bone and joint infections
•Peritonitis associated with dialysis in patient on CAPD.

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with any of the infections listed above.

Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Ceftazidime may be used in the peri-operative prophylaxis of urinary tract infections for patients
undergoing trans-urethral resection of the prostate (TURP).

The selection of ceftazidime should take into account its antibacterial spectrum, which is mainly restricted to aerobic Gram negative bacteria.

Ceftazidime should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum of activity.

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

להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים בצהוב) בעלון לרופא:

[..]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ceftazidime-Vit: each vial contains 1 g ceftazidime (as 1.164 g sterile ceftazidime pentahydrate).

Excipient with known effect:
Each vial contains 52.44 mg (2.28 mmol) of sodium.
For the full list of excipients, see section 6.1.

[..]

4.2. Posology and method of administration

Posology
Table 1: Adults and children ≥ 40 kg

Intermittent Administration	
Infection	Dose to be administered
Broncho-pulmonary infections in cystic fibrosis	100 to 150 mg/kg/day every 8 h, maximum 9 g per day1
Febrile neutropenia	2 g every 8 h
Nosocomial pneumonia	
Bacterial meningitis	
Bacteraemia*	
Bone and joint infections	1-2 g every 8 h
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	
Complicated urinary tract infections	1-2 g every 8 h or 12 h
Per-operative prophylaxis for transurethral resection of prostate (TURP)	1 g at induction of anaesthesia, and a second dose at catheter removal
Chronic suppurative otitis media	1 g to 2 g every 8 h
Malignant otitis externa	
Continuous infusion	
Infection	Dose to be administered
Febrile neutropenia	Loading dose of 2 g followed by a continuous infusion of 4 to 6 g every 24 h[1] The infusion of any unit of dissolved drug shall last no longer than 8h (see section 6.3). Therefore, following reconstitution, the unit dose in the infusion fluid should be administered within 8h, for example for 8 g per day: 2 g loading dose followed by 2 g continuous infusion every 8 h.
Nosocomial pneumonia	
Broncho-pulmonary infections in cystic fibrosis	
Bacterial meningitis	
Bacteraemia*	
Bone and joint infections	
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	

[1] In adults with normal renal function 9 g/day has been used without adverse effects.
*When associated with, or suspected to be associated with, any of the infections listed in 4.1.

[..]

Children < 40 kg

The safety and effectiveness of Ceftazidime-Vit administered as continuous infusion in renally impaired children < 40 kg has not been established, Close clinical monitoring for safety and efficacy is advised.

If continuous infusion is used in children with renal impairment, the creatinine clearance should be adjusted for body surface area or lean body mass.

Haemodialysis
The serum half-life during haemodialysis ranges from 3 to 5 h.

Following each haemodialysis period, the maintenance dose of ceftazidime recommended in tables 3 & 4 should be repeated.

[..]

Method of administration

The dose depends on the severity, susceptibility, site and type of infection and on the age and renal function of the patient.

Ceftazidime-Vit should be administered by intravenous injection or infusion, or by deep intramuscular injection. Recommended intramuscular injection sites are the upper outer quadrant of the gluteus maximus or lateral part of the thigh. Ceftazidime-Vit solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids. The standard recommended route of administration is by intravenous intermittent injection or intravenous continuous infusion. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient.
Ceftazidime-Vit solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids. The standard recommended route of administration is by intravenous intermittent injection or intravenous continuous infusion.

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4.4 Special warnings and precautions for use

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Ceftazidime- Vit contains 52.44 mg of sodium per vial (2.28 mmol) of sodium per vial, equivalent to 2.62% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This should be considered for patients who are on a controlled sodium diet.

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PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate (anhydrous sterile).

[..]

בברכה,

ויטאמד תעשיות פרמצבטיות בע"מ