VITAMED
REKAH GROUP
Pharmaceutical Industries LTD

ינואר 2025

עדכון עלון לרופא של התכשיר:
Ceftazidime - Vit 1 G
Powder for solution for injection

צוות רפואי נכבד,

חברת ויטאמד תעשיות פרמצבטיות בע"מ, מבקשת להודיעכם על עדכון העלון לרופא של התכשיר: **צפטזידים- ויט 1 ג'**.

שם התכשיר **צפטזידים-ויט** עודכן לשמו החדש: **צפטזידים- ויט 1 ג'**

ובהתאמה באנגלית, שם התכשיר **Ceftazidime-Vit** עודכן לשמו החדש: **Ceftazidime - Vit 1 G**.

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא, למידע מלא יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות. ניתן לעיין בכתובת:

https://israeldrugs.health.gov.il/#!/medDetails/159%2020%2034855%2000

כמו כן, ניתן לקבלו מודפס 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 בעלון לרופא: התוספות סומנו בצבע כחול, ההחמרות סומנו בצהוב והמחיקות סומנו בצבע אדום עם קו מחיקה.

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4. CLINICAL PARTICULARS

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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 day[1]

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	
[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.	

Table 2: Children < 40 kg

Infants and toddlers >2 months and children <40 kg	Infection	Usual dose
Intermittent Administration		
	Complicated urinary tract infections	100-150 mg/kg/day in three divided doses, maximum 6 g/day
	Chronic suppurative otitis media	
	Malignant otitis externa	
	Neutropenic children	150 mg/kg/day in three divided doses, maximum 6 g/day
	Broncho-pulmonary infections in cystic fibrosis	
	Bacterial meningitis	
	Bacteraemia*	
	Bone and joint infections	100 – 150 mg/kg/day in three divided doses, maximum 6 g/day
	Complicated skin and soft tissue infections	

	Complicated intra-abdominal infections	
	Peritonitis associated with dialysis in patients on CAPD	
Intermittent Administration		
	Most infections	25-60 mg/kg/day in two divided doses[1]
[1] In neonates and infants ≤ 2 months, the serum half-life of ceftazidime can be three to four times than in adults. * Where associated with, or suspected to be associated with, any of the infections listed in section 4.1.		

Elderly
In view of the age related reduced clearance of ceftazidime in elderly patients, the daily dose should not normally exceed 3 g in those over 80 years of age.

Hepatic impairment
Available data do not indicate the need for dose adjustment in mild or moderate liver function impairment. There are no study data in patients with severe hepatic impairment (see also section 5.2). Close clinical monitoring for safety and efficacy is advised.

Renal impairment
Ceftazidime is excreted unchanged by the kidneys. Therefore, in patients with impaired renal function, the dosage should be reduced (see also section 4.4).

An initial loading dose of 1 g should be given. Maintenance doses should be based on creatinine clearance:

Table 3: Recommended maintenance doses of **Ceftazidime-Vit 1 G** in renal impairment – intermittent infusion

Adults and children ≥ 40 kg

Creatinine clearance ml/min	Approx. serum creatinine µmol/l(mg/dl)	Recommended unit dose of **Ceftazidime-Vit 1 G** (g)	Frequency of dosing (hourly)
50-31	150-200 (1.7-2.3)	1	12
30-16	200-350 (2.3-4.0)	1	24
15-6	350-500 (4.0-5.6)	0.5	24

<5	>500 (>5.6)	0.5	48

In patients with severe infections the unit dose should be increased by 50% or the dosing frequency increased. In children the creatinine clearance should be adjusted for body surface area or lean body mass.

Children < 40 kg

Creatinine clearance (ml/min)**	Approx. serum creatinine* µmol/l (mg/dl)	Recommended individual dose mg/kg body weight	Frequency of dosing (hourly)
50-31	150-200 (1.7-2.3)	25	12
30-16	200-350 (2.3-4.0)	25	24
15-6	350-500 (4.0-5.6)	12 .5	24
<5	>500 (>5.6)	12 .5	48
* The serum creatinine values are guideline values that may not indicate exactly the same degree of reduction for all patients with reduced renal function. ** Estimated based on body surface area, or measured.			

Close clinical monitoring for safety and efficacy is advised.

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

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

Peritoneal dialysis
Ceftazidime may be used in peritoneal dialysis and continuous ambulatory peritoneal dialysis (CAPD).

In addition to intravenous use, ceftazidime can be incorporated into the dialysis fluid (usually 125 to 250 mg for 2 liters of dialysis solution).

For patients in renal failure on continuous arterio-venous haemodialysis or high-flux haemofiltration in intensive therapy units: 1 g daily either as a single dose or in divided doses. For low-flux haemofiltration, follow the dose recommended

under renal impairment.

For patients on veno-venous haemofiltration and veno-venous haemodialysis, follow the dosage recommendations in tables 4 & 5 below.

Table 4: Continuous veno-venous haemofiltration dose guidelines

Residual renal function (creatinine clearance ml/min)	Maintenance dose (mg) for an ultrafiltration rate (ml/min) of[1]:			
	5	16.7	33.3	50
0	250	250	500	500
5	250	250	500	500
10	250	500	500	750
15	250	500	500	750
20	500	500	500	750
[1] Maintenance dose to be administered every 12 h.				

Table 5: Continuous veno-venous haemodialysis dose guidelines

Residual renal function (creatinine clearance in ml/min)	Maintenance dose (mg) for a dialysate in flow rate of [1]:					
	1.0 liter/h			2.0 liter/h		
	Ultrafiltration rate (liter/h)			Ultrafiltration rate (liter/h)		
	0.5	1.0	2.0	0.5	1.0	2.0
0	500	500	500	500	500	750
5	500	500	750	500	500	750
10	500	500	750	500	750	1000
15	500	750	750	750	750	1000
20	750	750	1000	750	750	1000
[1] Maintenance dose to be administered every 12 h.						

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 1 G should be administered by intravenous injection 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 1 G** 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. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient.
Ceftazidime-Vit 1 G 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.

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6 PHARMACEUTICAL PARTICULARS

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6.3. Shelf life

The expiry date is indicated on the packaging materials.
After reconstitution:
Chemical and physical stability has been demonstrated for 24 hours at 2-8˚C for I.V administration. For I.M administration the solution should be injected immediately.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally be no longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

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6.6. Special precautions for disposal and other handling

Instructions for reconstitution
See table 6for addition volumes and solution concentrations, which may be useful when fractional doses are required.

Table 6: Powder for Solution for Injection

Vial size		Amount of diluent to be added (ml)	Approximate concentration (mg/ml)
1 g	Intramuscular Intravenous bolus	3 ml 10 ml	286 95

Note:
- The resulting volume of the solution of ceftazidime in reconstitution medium is increased due to the displacement factor of the drug product resulting in

the listed concentrations in mg/ml presented in the above table.

Solutions range in colour from light yellow to amber depending on concentration, diluent and storage conditions used. Within the stated recommendations, product potency is not adversely affected by such colour variations.

Ceftazidime at concentrations between 1 mg/ml and 40 mg/ml is compatible with:

- sodium chloride 9 mg/ml (0.9%) solution for injection
- M/6 sodium lactate injection
- compound sodium lactate injection (Hartmann's solution)
- 5% dextrose injection
- 0.225% sodium chloride and 5% dextrose injection
- 0.45% sodium chloride and 5% dextrose injection
- 0.9% sodium chloride and 5% dextrose injection
- 0.18% sodium chloride and 4% dextrose injection
- 10% dextrose injection
- Dextran 40 injection 10% in 0.9% sodium chloride injection
- Dextran 40 injection 10% in 5% dextrose injection
- Dextran 70 injection 6% in 0.9% sodium chloride injection
- Dextran 70 injection 6% in 5% dextrose injection

Ceftazidime at concentrations between 0.05 mg/ml and 0.25 mg/ml is compatible with Intra-peritoneal Dialysis Fluid (Lactate).

Ceftazidime at concentrations detailed in Table 6 may be constituted for intramuscular use with 0.5% or 1% Lidocaine Hydrochloride Injection.

Preparation of solutions for bolus injection

1. Insert the syringe needle through the vial closure and inject the recommended volume of diluent. The vacuum may assist entry of the diluent. Remove the syringe needle.
2. Shake to dissolve: carbon dioxide is released and a clear solution will be obtained in about 1 to 2 minutes.
3. Invert the vial. With the syringe plunger fully depressed, insert the needle through the vial closure and withdraw the total volume of solution into the syringe (the pressure in the vial may aid withdrawal). Ensure that the needle remains within the solution and does not enter the head space. The withdrawn solution may contain small bubbles of carbon dioxide; they may be disregarded.

These solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids. Ceftazidime is compatible with the intravenous fluids listed above.

Any residual antibiotic solution should be discarded.

Solutions of **Ceftazidime-Vit 1 G** range from light yellow to amber.
Solutions should be clear and practically free from particles.

For single use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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בברכה,

ויטאמד תעשיות פרמצבטיות בע"מ