

אפריל 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'.

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://israel.drugs.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: המחיקות סומנו בצבע אדום עם קו מחיקה.

[...]

4. CLINICAL PARTICULARS

[...]

4.2 Posology and method of administration

Posology

[...]

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. 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.

[...]

6 PHARMACEUTICAL PARTICULARS

[...]

6.6 Special precautions for disposal and other handling

Instructions for reconstitution

See table 4 for addition volumes and solution concentrations, which may be useful when fractional doses are required.

Table 4: Powder for Solution for Injection

Vial size		Amount of diluent to be added (ml)	Approximate concentration (mg/ml)
1 g	Intramuscular	3 ml	286
	Intravenous bolus	10 ml	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 detailed in Table 4 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. 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.

[...]

ברכה,

ויטאמד תעשיות פרמצבטיות בע"מ