

אפריל 2025

עדכון עלון לרופא של התכשיר:
Cefazolin-VIT
powder for solution for injection or infusion

צוות רפואי נכבד,

חברת ויטאמד תעשיות פרמצבטיות בע"מ, מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:
צפזולין-ויט.

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/160%2081%2035045%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 1.048 g cefazolin sodium (equivalent to 1.0 g cefazolin).

התוויה מאושרת:

Treatment of serious infections caused by susceptible organisms and also perioperatively for prophylaxis.

Treatment Respiratory tract:

Respiratory tract infections due to streptococcus pneumoniae (formerly diplococcus pneumoniae), klebsiella species, haemophilus influenzae, staphylococcus aureus (penicillin- sensitive and penicillin-resistant) and group A beta-hemolytic streptococci.

Cefazolin is effective in the eradication of streptococci from the nasopharynx. However, data establishing the efficacy of cefazolin in the subsequent prevention of rheumatic fever are not available at present.

Urinary tract:

Infections due to escherichia coli, klebsiella species, proteus mirabilis and some strains of Enterobacter and enterococci.

Skin and skin structure:

-hemolytic beta Infections due to Staphylococcus aureus (penicillin-sensitive and penicillin-resistant) group A streptococci and other strains of streptococci.

Biliary tract:

Infections due to escherichia coli, various strains of streptococci, proteus mirabilis, klebsiella species and staphylococcus aureus.

Bone and joint:

Infections due to staphylococcus aureus.

Genital infections (i.e. prostatitis epididymitis) due to escherichia coli, proteus mirabilis, klebsiella species and some strains of enterococci.

Septicemia due to streptococcus pneumoniae (formerly diplococcus pneumoniae), staphylococcus aureus (penicillin-sensitive and penicillin-resistant), proteus mirabilis, escherichia coli and klebsiella species.

Endocarditis caused by staphylococcus aureus (penicillin-sensitive and penicillin-resistant) and group A beta-hemolytic streptococci.

Appropriate culture and susceptibility studies should be performed to determine the susceptibility of the causative organism to cefazolin.

Perioperative prophylaxis:

The prophylactic administration of cefazolin perioperatively (preoperatively, intraoperatively and postoperatively) may reduce the incidence of certain postoperative infections in patients undergoing surgical procedures (e.g. hysterectomy, gastrointestinal surgery and transurethral prostatectomy) that are classified as contaminated or potentially contaminated.

The perioperative use of cefazolin may also be effective in surgical patients in whom infection at the operative site would present a serious risk (e.g. open-heart surgery and prosthetic arthroplasty).

להלן העדכונים בעלון לרופא: ראה מסומן ברקע צהוב.

[...]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cefazolin-VIT powder for solution for injection **or infusion**.

Each vial contains 1.048 g cefazolin sodium (equivalent to 1.0 g cefazolin).

Excipient(s) with known effect:

The sodium content of each vial is 2.2 mmol (50.6 mg).

3. PHARMACEUTICAL FORM

Powder for solution for injection **or infusion**.

The powder is white or almost white.

4. CLINICAL PARTICULARS

[...]

Posology and method of administration

[...]

Intravenous administration

For preparation of solutions for I.V. injection or infusion, the powder is dissolved in water for injections.

Cefazolin-VIT- powder for solution for injection **or infusion**:

For each gram of powder, at least 4 ml of the solvent must be used.

Preparation of solution for I.V. infusion: The reconstituted solution (prepared as described above) has to be transferred into a suitable infusion bag or bottle with 50-100 ml of one the following diluents:

- 0.9% Sodium Chloride
- Lactated Ringer's Injection
- 5% Glucose and 0.9% Sodium Chloride
- 10% Glucose Injection
- 5% Glucose Injection

[...]

בברכה,

ויטאמד תעשיות פרמצבטיות בע"מ