

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

Cefazolin Vit

חברת ויטמד מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

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

מרכיב פעיל:

CEFAZOLIN (AS SODIUM) 1000 MG/VIAL

צורת המתן של התכשיר :

I.M , I.V

עלון לרופא):

4.3) Contraindications:

Simultaneous administration is Contraindicated

Antibiotics

Cefazolin must not be used together with antibiotics which have a bacteriostatic mode of action (e.g. tetracyclines, sulfonamides, erythromycin, chloramphenicol) since antagonistic effects were observed in *in-vitro* tests (see section 4.5).

4.4) Special warnings and precautions for use:

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Cases of antibiotic-associated colitis have been reported in almost all antibiotics, the severity of which can range from mild to life threatening (see section 4.8). Therefore it is important to be mindful of this diagnosis in patients who experience diarrhoea **during or after using an antibiotic**. In the event of antibiotic-associated colitis, cefazolin should be discontinued immediately, a doctor consulted, and appropriate treatment initiated. Anti- peristaltic medicinal products are contraindicated in this situation. With long-term use of cefazolin, non-sensitive pathogens can get out of control. Close monitoring of the patient is therefore essential. If a superinfection occurs during treatment, appropriate measures **must be taken**.

-Long-term or high-dose therapy Regular check of organ system functions, including renal, hepatic and hematopoietic function, is advisable during long-term or high-dose treatment. **Elevated liver enzymes and changes in blood cells have been reported (see section 4.8).**

Intrathecal administration

Not for intrathecal administration. **Severe central nervous system intoxications (including convulsions) were reported following intrathecal administration of cefazolin.**



4.7) Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, there may be side effects (e.g. allergic reactions, dizziness) which may affect the ability to drive and use machines (see section 4.8).

4.8) Undesirable effects:

System organ class	Common	Uncommon	Rare
Infections and infestations			Rhinitis
Blood and lymphatic system disorders		haemolytic anaemia, granulocytosis, leukocytosis, monocytosis, lymphocytopenia, basophilia	
Metabolism and nutrition disorders			Hyperglycaemia, hypoglycaemia
Nervous system disorders			dizziness
Respiratory, thoracic and mediastinal disorders			Pleural effusion, dyspnoea or respiratory distress, cough
Gastrointestinal disorders	vomiting		



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Skin and subcutaneous tissue disorders	Rash	Erythema multiforme, angioedema	Toxic epidermal necrolysis, Stevens-Johnson syndrome
Hepatobiliary disorders			Temporary increase in GGT, bilirubin and/or LDH
General disorders and administration			Malaise, fatigue, chest pain

השינויים המודגשים ברקע צהוב מהווים החמרה. בעלון בוצעו שינויים נוספים אשר מהווים תוספת מידע.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות:
<https://data.health.gov.il/drugs/index.html#!/byDrug>
ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת ויטמד

בברכה,

מירי חזן
רוקחת ממונה