



ינואר 2021

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של **ZINFORO** :
זינפורו

הודעה זו מפרטת עדכונים המהווים החמרה במידע הבטיחותי (מסומנים עם רקע צהוב בגוף ההודעה), למידע מלא יש לעיין בעלון המאושר.

המרכיב הפעיל:

CEFTAROLINE FOSAMIL 600 mg

Indicated for:

Zinforo is indicated in adults and children from age of 2 months for the treatment of the following infections (see sections 4.4 and 5.1):

- *Complicated skin and soft tissue infections (cSSTI)*
- *Community-acquired pneumonia (CAP)*

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

להלן העדכונים העיקריים בעלון לרופא:

4.8 Undesirable effects

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Tabulated list of adverse reactions

The following adverse reactions have been identified during clinical trials and post-marketing experience with Zinforo. Adverse reactions are classified according to System Organ Class and frequency. Frequency categories are derived according to the following conventions: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), not known (cannot be estimated from the available data).

Table 5 Frequency of adverse reactions by system organ class from clinical trials and post-marketing experience

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System organ class	Very common	Common	Uncommon	Rare	Not known
Nervous system disorders		Headache, dizziness	Encephalopathy* ⁺		

System organ class	Very common	Common	Uncommon	Rare	Not known
Respiratory, thoracic and mediastinal disorders					Eosinophilic pneumonia*

* Adverse Drug Reaction (ADR) identified post-marketing.

+ Risk of encephalopathy is higher in patients with renal impairment in whom the dose of ceftaroline has not been appropriately reduced (see sections 4.2 and 4.9).

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4.9 Overdose

Limited data in patients receiving higher than recommended Zinforo dosages show similar adverse reactions as observed in the patients receiving recommended dosages. Treatment of overdose should follow standard medical practice.

Patients with renal impairment

Relative overdosing could occur in patients with moderate renal impairment. Neurological sequelae, including encephalopathy, have been noted in cases where beta-lactam antibiotics (including cephalosporins) have been given to patients with impaired renal function without reducing the dose (see section 4.2).

Ceftaroline can be removed by haemodialysis; over a 4 hour dialysis period, approximately 74% of a given dose was recovered in the dialysate.

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

<https://data.health.gov.il/drugs/index.html#!/byDrug>

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פיזור PFE פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
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