



אפריל 2024

פיזור פי אף אי פרמצבטיקה ישראל בע"מ  
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רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכונים בעלון לרופא של **Zavicefta** - זביספטא:  
Powder for concentrate for solution for infusion  
המרכיבים הפעילים:

ceftazidime pentahydrate equivalent to 2 g ceftazidime  
avibactam sodium equivalent to 0.5 g avibactam

להלן העדכונים העיקריים בעלון לרופא:

#### 4.4 Special warnings and precautions for use

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##### Hypersensitivity reactions

Serious and occasionally fatal hypersensitivity reactions are possible (see sections 4.3 and 4.8). In case of hypersensitivity reactions, treatment with Zavicefta® must be discontinued immediately and adequate emergency measures must be initiated .

There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction, see section 4.8).

Before beginning treatment, it should be established whether the patient has a history of hypersensitivity reactions to ceftazidime, to other cephalosporins or to any other type of  $\beta$ -lactam antibacterial agent. Caution should be used if ceftazidime/avibactam is given to patients with a history of non-severe hypersensitivity to penicillins, monobactams or carbapenems

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#### 4.8 Undesirable effects

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##### Tabulated list of adverse reactions

The following adverse reactions have been reported with ceftazidime alone and/or identified during the Phase 2 and Phase 3 trials with Zavicefta®. Adverse reactions are classified according to frequency and System Organ Class. Frequency categories are derived from adverse reactions and/or potentially clinically significant laboratory abnormalities, and are defined according to the following conventions:

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  and  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  and  $< 1/100$ )

Rare ( $\geq 1/10,000$  and  $< 1/1,000$ )

Very rare ( $< 1/10,000$ )

Unknown (cannot be estimated from the available data)

Table 6 Frequency of adverse reactions by system organ class

System Organ Class	Very common	Common	Uncommon	Very rare	Not known
...	...	...	...	...	...
Cardiac disorders					Kounis syndrome <sup>a,*</sup>
...	...	...	...	...	...

\* ADR identified post-marketing.

<sup>a</sup> Acute coronary syndrome associated with an allergic reaction.

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## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

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#### Susceptibility testing breakpoints

Minimum Inhibitory Concentration (MIC) breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for ceftazidime/avibactam can be viewed on the following website:

[https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints\\_en.xlsx](https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx)

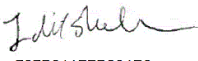
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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

<https://israeldrugs.health.gov.il/#!/byDrug>

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

בברכה,  
עידית שלם אבידר  
רוקחת ממונה

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