



מאי 2025

פיזור פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכונים בעלון לרופא של **Zavicefta** - **זביספטה**:
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

....

Hypersensitivity reactions

....

Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported with unknown frequency in association with ceftazidime treatment (see section 4.8).

Patients should be advised of the signs and symptoms and monitored closely for skin reactions.

If signs and symptoms suggestive of these reactions appear, Zavicefta should be withdrawn immediately, and an alternative treatment considered.

If the patient has developed a serious reaction such as SJS, TEN, DRESS or AGEPE with the use of ceftazidime, treatment with Zavicefta must not be restarted in this patient at any time.

....

4.8 Undesirable effects

...

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 ($< 1/10,000$)

Not known (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
...

Skin and subcutaneous tissue disorders		Rash maculopapular Urticaria Pruritus			Toxic epidermal necrolysis Stevens-Johnson syndrome Erythema multiforme Angioedema Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Acute generalised exanthematous pustulosis (AGEP)*
...

* ADR identified post-marketing.

^a Acute coronary syndrome associated with an allergic reaction.

...

6.3 Shelf life

...

Infusion syringes

If the intravenous solution is prepared with diluents listed in section 6.6 (ceftazidime concentration ≥ 8 mg/mL to 40 mg/mL), the chemical and physical in-use stability has been demonstrated (from initial vial puncture) for up to 6 hours at not more than 25°C.

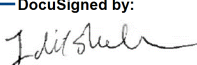
...

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

DocuSigned by:

737B811FFB204E6...