04/2025

Ceftriaxone - Fresenius
צפטריאקסון - פרזניוס
Powder For Solution For INJ/INF

רופא/ה, רוקח/ת נכבד/ה,
חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון. העלון עודכן בתאריך 04/2025.

ההתוויה הרשומה כיום בישראל לתכשיר:

Ceftriaxone -Fresenius is indicated for the treatment of the following infections in adults and children including term neonates (from birth):

- Bacterial Meningitis
- Community acquired pneumonia
- Hospital acquired pneumonia
- Acute otitis media
- Intra-abdominal infections
- Complicated urinary tract infections (including pyelonephritis)
- Infections of bones and joints
- Complicated skin and soft tissue infections
- Gonorrhoea
- Syphilis
- Bacterial endocarditis

Ceftriaxone -Fresenius may be used:

- For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults.
- For treatment of disseminated Lyme borreliosis [early (stage II) and late (stage III)] in adults and children including neonates from 15 days of age.
- For pre-operative prophylaxis of surgical site infections.
- In the management of neutropenic patients with fever that is suspected to be due to a ceftriaxone-susceptible bacterial infection.
- In the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Ceftriaxone -Fresenius should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum.
Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

מקראה לעדכונים המסומנים:
מידע שהוסר -מסומן בקו אדום חוצה ~~XXX~~
תוספת -כתב כחול
החמרה על רקע צהוב

להלן מתוארים העדכונים העיקריים בעלון לרופא, בעלון קיימים עדכונים נוספים.

2. Qualitative and quantitative composition

Each vial of Ceftriaxone contains 1193 mg of ceftriaxone sodium, equivalent to 1000 mg of ceftriaxone.

(…)

1g vial contains 3.6 mmol (or 82.3 mg) of sodium per vial.

3. Pharmaceutical form

(…)

Almost white or yellowish powder.

~~For I.V/I.M administration.~~

4.4 Special warnings and precautions for use

(…)

Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see section 4.8).

4.8 Undesirable effects

(…)

System Organ Class	Common	Uncommon	Rare	Not Known [a]
(…)				
Cardiac disorders				Kounis syndrome

(…)

5.1 Pharmacodynamic properties

(…)

Pathogen	Dilution Test (MIC, mg/L)	
	Susceptible	Resistant
(...)		
Haemophilus influenzae	≤ 0.12~~5~~	> 0.12~~5~~
Moraxella catarrhalis	≤ 1	> 2
Neisseria gonorrhoeae	≤ 0.12~~5~~	> 0.12~~5~~
Neisseria meningitidis	≤ 0.12~~5~~	> 0.12~~5~~
~~Kingella kingae~~	~~≤ 0.06~~	~~> 0.06~~
(...)		

6.6 Special precautions for disposal and other handling

(…)

~~From a microbiological point of view, the product must be used immediately. If not used immediately, in-use storage times and conditions prior to use are the only responsibility of the user and would not be longer than 24 hours at temperature ranging from +2 ºC and +8 ºC.~~

למידע נוסף יש לעיין בעלון לרופא המעודכן אשר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבל את עלון התכשיר מודפס על ידי פניה לבעל הרישום: ניאופרם (ישראל) 1996 בע"מ, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373753, פקס: 03-9373774

בברכה

עוז וולך, רוקח/ת ממונה של בעל הרישום