



מאי 2025

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת איי.אל.מדי-מרקט בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

CEFTRIAZONE MEDO 1 GR

צפטריאקסון מדו 1 גר'

חומר פעיל: CEFTRIAZONE (AS SODIUM) 1 G/VIAL

צורת מינון: POWDER FOR SOLUTION FOR INJ/INF

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Ceftriaxone 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 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 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.



ברצוננו להודיע שהעלון לרופא עודכן. בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות בצהוב, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה.

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4.4 Special warnings and precautions for use

Hypersensitivity reactions

As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported (see section 4.8).

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

In case of severe hypersensitivity reactions, treatment with ceftriaxone must be discontinued immediately and adequate emergency measures must be initiated. Before beginning treatment, it should be established whether the patient has a history of severe hypersensitivity reactions to ceftriaxone, to other cephalosporins or to any other type of beta-lactam agent. Caution should be used if ceftriaxone is given to patients with a history of non-severe hypersensitivity to other beta-lactam agents.

Severe cutaneous adverse reactions (Stevens Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis) and drug reaction with eosinophilia and systemic symptoms (DRESS) which can be life-threatening or fatal, have been reported in association of ceftriaxone treatment; ; however, the frequency of these events is not known (see section 4.8).

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4.8 Undesirable effects

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System Organ Class	Common	Uncommon	Rare	Not Known ^a
Cardiac disorders				Kounis syndrome

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Committee on Antimicrobial Susceptibility Testing (EUCAST v. 7.1, ~~valid from 2017-03-10~~) are as follows:

Pathogen	Dilution Test (MIC, mg/L)	
	Susceptible	Resistant
<i>Enterobacteriaceae</i>	≤ 1	> 2
<i>Staphylococcus</i> spp.	a.	a.
<i>Streptococcus</i> spp. (Groups A, B, C and G)	b.	b.
<i>Streptococcus pneumoniae</i>	≤ 0.5	> 2
Viridans group <i>Streptococci</i>	≤ 0.5	> 0.5
<i>Haemophilus influenzae</i>	≤ 0.125	> 0.125
<i>Moraxella catarrhalis</i>	≤ 1	> 2
<i>Neisseria gonorrhoeae</i>	≤ 0.125	> 0.125
<i>Neisseria meningitidis</i>	≤ 0.125	> 0.125
<i>Kingella kingae</i>	≤ 0.06	> 0.06
Non-species related	≤ 1	> 2

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6.5 Nature and contents of container

CEFTRIAXONE MEDO 1 GR is supplied in clear type I glass vials, nominal capacity 10 ml, sealed with a 20 mm diameter rubber stopper and an aluminium overcap (with or without a plastic flip-off seal), in a carton of 10 vials with a leaflet.

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העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות <https://israel drugs.health.gov.il>.

ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת איי.אל.מדי-מרקט בע"מ.