דצמבר 2023

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

CEFTRIAXONE MEDO 1 GR

צפטריאקסון מדו 1 גר'

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

צורת מינון: POWDER FOR SOLUTION FOR INJ/INF

עדכונים בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

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.

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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

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The presence of ceftriaxone may falsely lower estimated blood glucose values obtained with some blood glucose monitoring systems. Please refer to instructions for use for each system. Alternative testing methods should be used if necessary.

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Encephalopathy
Encephalopathy has been reported with the use of ceftriaxone (see section 4.8), particularly in elderly patients with severe renal impairment (see section 4.2) or central nervous system disorders. If ceftriaxone-associated encephalopathy is suspected (e.g. decreased level of consciousness, altered mental state, myoclonus, convulsions), discontinuation of ceftriaxone should be considered.

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4.8 Undesirable effects

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System Organ Class	Common	Uncommon	Rare	Not Known [a]
Infections and infestations		Genital fungal infection	Pseudomembranous colitis[b]	Superinfection[b]
Blood and lymphatic system disorders	Eosinophilia Leucopenia Thrombocytopenia	Granulocytopenia Anaemia Coagulopathy		Haemolytic anaemia[b] Agranulocytosis
Immune system disorders				Anaphylactic shock Anaphylactic reaction Anaphylactoid reaction Hypersensitivity[b] Jarisch-Herxheimer reaction[b]
Nervous system disorders		Headache Dizziness	Encephalopathy	Convulsion
Ear and labyrinth disorders				Vertigo
Respiratory, thoracic and mediastinal disorders			Bronchospasm	
Gastrointestinal disorders	Diarrhoea[b] Loose stools	Nausea Vomiting		Pancreatitis[b] Stomatitis Glossitis
Hepatobiliary disorders	Hepatic enzyme increased			Gall bladder precipitation[b] Kernicterus Hepatitis[c] Hepatitis cholestatic[b,c]
Skin and subcutaneous tissue disorders	Rash	Pruritus	Urticaria	Stevens Johnson Syndrome[b] Toxic epidermal necrolysis[b] Erythema multiform Acute generalised exanthematous Pustulosis Drug reaction

				with eosinophilia and systemic symptoms (DRESS)[b]
Renal and urinary disorders			Haematuria Glycosuria	Oliguria Renal precipitation (reversible)
General disorders and administration site conditions		Phlebitis Injection site pain Pyrexia	Oedema Chills	
Investigations		Blood creatinine increased		Coombs test false positive[b] Galactosaemia test false positive[b] Non enzymatic methods for glucose determination false positive[b]

[a] Based on post-marketing reports. Since these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency, which is therefore categorised as not known.

[b] See section 4.4

[c] Usually reversible upon discontinuation of ceftriaxone

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~~Cases of renal precipitation have been reported, primarily in children older than 3 years of age and who have been treated with either high daily doses (e.g. ≥ 80 mg/kg/day) or total doses exceeding 10 grams and who presented with other risk factors (e.g. fluid restrictions or confinement to bed). The risk of precipitate formation is increased in immobilized or dehydrated patients. This event may be symptomatic or asymptomatic, may lead to renal insufficiency and anuria, and is reversible upon discontinuation of ceftriaxone (see section 4.4).~~

Cases of ceftriaxone precipitation in the urinary tract have been reported, mostly in children treated with high doses (e.g. ≥ 80 mg/kg/day or total doses exceeding 10 grams) and who have other risk factors (e.g. dehydration, confinement to bed). This event may be asymptomatic or symptomatic, and may lead to ureteric obstruction and postrenal acute renal failure, but is usually reversible upon discontinuation of ceftriaxone (see section 4.4).

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~~Hepatitis~~

~~Cases of hepatitis including cases of hepatocellular injuries may have a serious or even life-threatening course.~~

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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 v. 7.1, valid from 2017-03-10) are as follows:

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

a. Susceptibility inferred from cefoxitin susceptibility.
b. Susceptibility inferred from benzylpenicillin susceptibility.
c. Isolates with a ceftriaxone MIC above the susceptible breakpoint are rare and, if found, should be re-tested and, if confirmed, should be sent to a reference laboratory.
d. Breakpoints apply to a daily intravenous dose of 1 g x 1 and a high dose of at least 2 g x 1.

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5.2 Pharmacokinetic properties

Absorption
Intramuscular administration

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Intravenous administration

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

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