מאי 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

# CEFOTAXIME MEDO 1 GR
# צפוטקסים מדו 1 גר'

חומר פעיל: CEFOTAXIME ( AS SODIUM ) 1 g / vial

צורת מינון: POWDER FOR SOLUTION FOR INJ/INF

עדכונים בעלון לצרכן במתכונת עלון לרופא

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

Cefotaxime Medo 1 gr is indicated in the treatment of the following infections either before the infecting organism has been identified or when caused by bacteria of established sensitivity.
Septicaemias
Respiratory Tract Infections such as acute and chronic bronchitis, bacterial pneumonia, infected bronchiectasis, lung abscess and post-operative chest infections.
Urinary Tract Infections such as acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.
Soft-Tissue Infections such as cellulitis, peritonitis and wound infections. Bone and Joint Infections such as osteomyelitis, septic arthritis.
Obstetric and Gynaecological Infections such as pelvic inflammatory disease.
Gonorrhoea particularly when penicillin has failed or is unsuitable.
Other Bacterial Infections such as meningitis and other sensitive infections suitable for parenteral antibiotic therapy.
PROPHYLAXIS: Prophylaxis of infections in patients with reduced resistance. Pre-operative prophylaxis in patients who are at increased risk from infection.

ברצוננו להודיע שהעלון לצרכן במתכונת עלון 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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~~Serious bullous reactions~~

~~Cases of serious bullous skin reactions like Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported with cefotaxime (see section 4.8). Patients should be advised to contact their doctor immediately prior to continuing treatment if skin and/or mucosal reactions occur.~~

Severe skin reactions

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

At the time of prescription patients should be advised of the signs and symptoms for skin reactions.

If signs and symptoms suggestive of these reactions appear, cefotaxime should be withdrawn immediately. If the patient has developed AGEP, SJS, TEN or DRESS with the use of cefotaxime, treatment with cefotaxime must not be restarted and should be permanently discontinued.

In children, the presentation of a rash can be mistaken for the underlying infection or an alternative infectious process, and physicians should consider the possibility of a reaction to cefotaxime in children that develop symptoms of rash and fever during therapy with cefotaxime.

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**4.8. Undesirable effects**

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| *System organ class* | *Very Common (≥1/10)* | *Uncommon (≥1/1,000 to <1/100)* | *Rare (≥1/10,000 to <1/1,000)* | *Very rare (<1/10,000)* | *Not known (cannot be estimated from available data)* |
|---|---|---|---|---|---|
| *Skin and subcutaneous tissue disorders* | | Rash<br>Pruritus<br>Urticaria | | | Erythema multiforme<br>Stevens-Johnson syndrome<br>Toxic epidermal necrolysis (see section 4.4)<br>Acute generalised exanthematous pustulosis (AGEP)<br>Drug reaction with eosinophilia and systemic symptoms (DRESS) (see section 4.4) |

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