



יולי 2023

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

התוויה כפי שאושרה בתעודת הרישום:

Imetoxim 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 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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Since cross allergy exists between penicillins and cephalosporins, use of the latter should be undertaken with extreme caution in penicillin sensitive subjects.

Hypersensitivity reactions (anaphylaxis) occurring with these two antibiotic families may be serious or even fatal.

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Encephalopathy

Beta-lactams, including cefotaxime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment (see section 4.8).

Neurotoxicity

High doses of beta-lactam antibiotics, including cefotaxime, particularly in patients with renal insufficiency, may result in encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions) (see section 4.8).

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4.7. Effects on ability to drive and use machines

In the case of side-effects adverse reactions such as dizziness or encephalopathy (which may include convulsions, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle's ability to concentrate and to react properly may be impaired. In such cases, patients should refrain from driving cars and using machines. High doses of cefotaxime, particularly in patients with renal insufficiency, may cause encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions) (see section 4.8). Patients should be advised not to drive or operate machinery if any such symptoms occur.

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4.8. Undesirable effects

System organ class	Very Common ($\geq 1/10$)	Uncommon ($\geq 1/1,000$ to $< 1/100$)	Rare ($\geq 1/10,000$ to $< 1/1,000$)	Very rare ($< 1/10,000$)	Not known (cannot be estimated from available data)
Nervous system disorders		Convulsions (see section 4.4)			Headache Dizziness Encephalopathy (e.g. impairment of consciousness, abnormal movements) (see section 4.4)

*Beta-lactams, including cefotaxime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment

... A.L. medicine and medical equipment

העלון לצרכן 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.