



ספטמבר 2023

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

AMIKACIN - MEDO

אמיקצין – מדו

חומר פעיל: AMIKACIN (AS SULFATE) 250 mg / 1 ml

צורת מינון: SOLUTION FOR INJECTION / INFUSION

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

AMIKACIN - MEDO is indicated in the short-term treatment of Gram-negative organisms, including pseudomonas and some Gram-positive organisms.

Sensitive Gram-negative organisms include; Pseudomonas aeruginosa, Escherichia coli., indole-positive and indole-negative Proteus spp., Klebsiella, Enterobacter and Serratia spp., Minea-Herralae, Citrobacter freundii, Salmonella, Shigella, Acinetobacter and Providencia spp.

The principal Gram-positive organism sensitive to amikacin is Staphylococcus aureus, including some methicillin-resistant strains. AMIKACIN - MEDO has some activity against other Gram-positive organisms including certain strains of Streptococcus pyogenes, Enterococci and Diplococcus pneumoniae.

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

4.3 Contraindications

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Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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Ototoxicity

The risk of ototoxicity due to aminoglycosides increases with the degree of exposure to either persistently high peak or high trough serum concentrations. Patients developing cochlear or vestibular damage may not have symptoms during therapy to warn them of developing eighth nerve toxicity, and total or partial irreversible bilateral deafness or disabling vertigo may occur after the drug has been discontinued. Aminoglycoside-induced ototoxicity is usually irreversible.



Patients with mitochondrial DNA mutations, particularly the nucleotide 1555 A to G substitution in the 12S rRNA gene may be at higher risk for ototoxicity, even if the patient's aminoglycoside serum levels were within the recommended range. In case of family history of aminoglycoside-induced deafness or known mitochondrial DNA mutations in the 12S rRNA gene, alternative treatments other than aminoglycosides should be considered.

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Other

Aminoglycosides are quickly and almost totally absorbed when they are applied topically, except to the urinary bladder, in association with surgical procedures. Irreversible deafness, renal failure and death due to neuromuscular blockade have been reported following irrigation of both small and large surgical fields with an aminoglycoside preparation.

As with other antibiotics, the use of amikacin may result in overgrowth of non-susceptible organisms. If this occurs, appropriate therapy should be instituted.

Macular infarction sometimes leading to permanent loss of vision has been reported following intravitreal administration (injection into the eye) of amikacin. Amikacin-Medo 500mg/2ml solution for injection/infusion contains 0.65 mmol sodium per 2 ml. This medicinal product contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially 'sodium-free'.

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6.6 Special precautions for disposal and other handling

Single use only. Discard any unused contents.

The solution may darken from colourless to a pale yellow but this does not indicate a loss of potency. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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 א.י.אל.מדי-מרקט בע"מ.