



פברואר 2024

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.

4.4 Special warnings and precautions for use

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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.~~

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4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of amikacin in pregnancy has not yet been established.

Amikacin should be administered to pregnant women and neonatal infants only when clearly needed and under medical supervision (see section 4.4).

There are limited data on use of aminoglycosides in pregnancy. Aminoglycosides can cause foetal harm. Aminoglycosides cross the placenta and there have been reports of total, irreversible, bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Adverse effects on the foetus or newborns have not been reported in pregnant women treated with other aminoglycosides, therefore, the potential for harm exists. If amikacin is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the foetus.

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4.8 Undesirable effects

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Macular infarction sometimes leading to permanent loss of vision has been reported following intravitreal administration (injection into the eye) of amikacin.

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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](https://israel drugs.health.gov.il)

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