אוקטובר 2021

TAVANIC 500 MG solution for I.V. infusion

חומר פעיל: LEVOFLOXACIN (AS HEMIHYDRATE) 5 MG/ML

ההתוויה המאושרת:

In adults for whom intravenous therapy is considered to be appropriate, Tavanic solution for infusion is indicated for the treatment of the following infections when due to levofloxacin - susceptible micro-organisms:
Community- acquired pneumonia,
Complicated urinary tract infections including pyelonephritis,
Skin and soft tissue infections.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לצרכן ('בפורמט עלון לרופא') בספטמבר 2021.

העדכונים העיקרים הינם:

4.4 Special warnings and precautions for use

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Aortic aAneurysm and sDissection, and heart valve regurgitation/incompetence

Epidemiologic studies report an increased risk of aortic aneurysm and dissection, particularly in elderly patients, and of aortic and mitral valve regurgitation after intake of fluoroquinolones~~, particularly in the older population~~.
Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones (see section 4.8).

Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease or congenital heart valve disease,
or in patients diagnosed with pre-existing aortic aneurysm and/or ~~aortic~~ dissection or heart valve disease~~,~~ or in presence of
other risk factors or conditions predisposing ~~for aortic aneurysm and dissection (e.g., Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, known atherosclerosis).~~

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- for both aortic aneurysm and dissection and heart valve regurgitation/incompetence (e.g. connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome, Turner syndrome, Behcet's disease, hypertension, rheumatoid arthritis) or additionally
- for aortic aneurysm and dissection (e.g. vascular disorders such as Takayasu arteritis or giant cell arteritis, or known atherosclerosis, or Sjogren's syndrome) or additionally
- for heart valve regurgitation/incompetence (e.g. infective endocarditis).

The risk of aortic aneurysm and dissection, and their rupture may also be increased in patients treated concurrently with systemic corticosteroids.

In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department.

Patients should be advised to seek immediate medical attention in case of acute dyspnoea, new onset of heart palpitations, or development of oedema of the abdomen or lower extremities.

Tavanic contains sodium
This medicinal product contains up to 363 mg sodium per bottle, equivalent to 18% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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4.7 Effects on ability to drive and use machines

Tavanic has minor or moderate influence on the ability to drive and use machines. Some undesirable effects (e.g., dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g., driving a car or operating machinery).

4.8 Undesirable effects

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Table of adverse reactions

System organ class

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Cardiac disorders**

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Vascular disorders**

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** Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones (see section 4.4)

5.1 Pharmacodynamic properties

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Breakpoints

The EUCAST recommended MIC breakpoints for levofloxacin, separating susceptible from ~~intermediately~~ susceptible increased exposure organisms and ~~intermediately~~ susceptible increased exposure from resistant organisms are presented in the below table for MIC testing (mg/l).

EUCAST clinical MIC breakpoints for levofloxacin (version ~~2~~10.0, ~~2012~~2020-01-01):

Pathogen	Susceptible	Resistant
~~Enterobacteriaceae~~Enterobacterales	≤0.5~~1~~ mg/l	>~~2~~ 1 mg/l
Pseudomonas spp.	≤0.001 mg/l	>~~2~~ 1 mg/l
Acinetobacter spp.	≤~~1~~ 0.5 mg/l	>~~2~~ 1 mg/l
Staphylococcus aureus Coagulase-negative staphylococci ~~*Staphylococcus spp.*~~	≤0.001 mg/l	>1~~2~~ mg/l
Enterococcus spp.[1]	≤4 mg/l	>4 mg/l
Streptococcus ~~*S.*~~ *pneumoniae* [1]	≤~~2~~ 0.001 mg/l	>2 mg/l
Streptococcus groups A, B, C and ~~,~~ G	≤~~1~~ 0.001 mg/l	>2 mg/l
Haemophilus ~~*H.*~~ *influenzae* [2,3]	≤~~1~~ 0.06 mg/l	>~~1~~ 0.06 mg/l
Moraxella ~~*M.*~~ *catarrhalis* [3]	≤~~1~~0.125 mg/l	>0.125 ~~1~~ mg/l
Helicobacter pylori	≤1 mg/l	>1 mg/l
Aerococcus sanguinicola and urinae[2]	≤2 mg/l	>2 mg/l
Aeromonas spp.	≤0.5 mg/l	>1 mg/l
PK-PD (Non-species related) breakpoints [4]	≤~~1~~ 0.5 mg/l	>~~2~~ 1 mg/l

~~[1] The breakpoints for levofloxacin relate to high dose therapy.~~
~~[2] Low-level fluoroquinolone resistance (ciprofloxacin MICs of 0.12-0.5 mg/l) may occur but there is no evidence that this resistance is of clinical importance in respiratory tract infections with *H. influenzae*.~~
~~[3] Strains with MIC values above the susceptible breakpoint are very rare or not yet reported. The identification and antimicrobial susceptibility tests on any such isolate must be repeated and if the result is confirmed the isolate must be sent to a reference laboratory. Until there is evidence regarding clinical response for confirmed isolates with MIC above the current resistant breakpoint, they should be reported resistant.~~
~~[4] Breakpoints apply to an oral dose of 500 mg x 1 to 500 mg x 2 and an intravenous dose of 500 mg x 1 to 500 mg x 2.~~
1: uncomplicated urinary tract infections only
2: Susceptibility can be inferred from ciprofloxacin susceptibility

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום- סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון : 09-8633700 .

להלן הקישור לאתר משרד הבריאות: https://data.health.gov.il/drugs/index.html#/byDrug

בברכה,

ענבל גבע-דותן
רוקחת ממונה

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