

04/2022

רופא/ה, רוקח/ת נכבד/ה,  
חברת ג'נמדיקס מקבוצת ניאופרם מבקשת להודיעך על עדכון העלון לרופא של התכשיר:

**VANCOMYCIN MYLAN 500 MG,  
VANCOMYCIN MYLAN 1000 MG,  
LYOPHILIZED POWDER FOR CONCENTRATED  
SOLUTION**

**I.V , ORAL**

VANCOMYCIN (AS HYDROCHLORIDE) 1 G/VIAL, 500 MG/VIAL החומר הפעיל וכמותו

MYLAN S.A.S., 117 ALLEE DES PARCS, 69800 SAINT PRIEST, FRANCE שם היצרן וכתובתו:

ג'נמדיקס, ת.ד. 7063, השילוח 6 פתח תקווה שם בעל הרישום וכתובתו:

**להלן נוסח ההתוויה המאושר לתכשיר:**

Vancomycin hydrochloride is indicated for the treatment of severe or serious infections due to susceptible strains of methicillin - resistant (beta-lactam-resistant) staphylococci.  
It is also indicated for administration to penicillin-allergic patients as well patients who have failed to respond to or who cannot receive other drugs including cephalosporins or penicillins and for infections due to vancomycin-susceptible organisms that are resistant to other antimicrobial drugs.  
Vancomycin hydrochloride is indicated for first-line therapy when methicillin-resistant staphylococci are suspected but when susceptibility data become available appropriate therapy should be instituted.  
Vancomycin hydrochloride is effective in the treatment of staphylococcal endocarditis as well as in other infections due to staphylococci including lower respiratory tract infections septicemia skin and skin - structure infection and bone infections.  
Antibiotic therapy is as an adjunct to appropriate surgical measures when staphylococcal infections are purulent and localized.  
For endocarditis due to Streptococcus viridans or Streptococcus bovis vancomycin hydrochloride has been shown to be effective in combination with an aminoglycoside.  
Vancomycin hydrochloride has been shown to be effective only in combination with an aminoglycoside for endocarditis due to enterococci (eg Enterococcus faecalis).  
Vancomycin hydrochloride has been shown to be effective for the treatment of diphtheroid endocarditis. In early-onset prosthetic valve endocarditis caused by Staphylococcus epidermidis or diphtheroids vancomycin hydrochloride has been administered successfully in combination with either rifampin an aminoglycoside or combined with both drugs.  
Bacteriologic cultures of specimens should be obtained for isolation and identification of causative organisms and determination of susceptibilities to vancomycin hydrochloride.  
Oral Therapy Vancomycin hydrochloride injection may be given orally for the treatment of antibiotic-associated Pseudomembranous colitis due to Staphylococcus enterocolitis and Clostridium difficile.  
Vancomycin hydrochloride is not effective orally when administered for other types of infection.

העדכון בעלון הוא: שם התכשיר השתנה: מ- Vancomycin Mylan 1 G ל- Vancomycin Mylan 1000 MG.

- העלון לרופא המעודכן נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות.
- ניתן לקבל את העלון מודפס על ידי פניה ישירה לבעל הרישום:  
ג'נמדיקס, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001, טלפון: 03-9373737.

בברכה,

אבי ילצינדג  
רוקח ממונה  
בעל הרישום: ג'נמדיקס