

מרץ 2026

Vancomycin Viatris 500 mg, Vancomycin Viatris 1000 Mg

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים: ונקומיצין ויאטריס 500 מ"ג, 1000 מ"ג.

בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Each vial of Lyophilized Powder for Concentrated Solution contains: Vancomycin (as hydrochloride) 500 mg or 1000 mg respectively.

התוויות מאושרות:

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 (e.g. 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.

העלון לרופא עודכן בתאריך מרץ 2026. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

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4.4. Special warnings and precautions for use

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Cardiovascular and cerebrovascular effects

Cases of Kounis syndrome have been reported in patients treated with vancomycin. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitivity reaction associated with constriction of the coronary arteries, which may lead to myocardial infarction.

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4.8. Undesirable effects

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Blood and the lymphatic system disorders

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Not known: Hemolytic anemia

Hepatobiliary disorders

Common: Alanine aminotransferase increased, aspartate aminotransferase increased

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Cardiac disorders

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Not known: Kounis syndrome