

נספח 1:

הודעה על הפסקת שיווק זמנית

תאריך ההודעה: 09.11.2023

בעל הרישום GENMEDIX, ISRAEL מודיע על הפסקת שיווק זמנית של:

123-64-30298-00	מספר רישום
ונקומיצין ויאטריס 1000 מ"ג	שם התכשיר בעברית
VANCOMYCIN VIATRIS 1000 MG	שם התכשיר באנגלית
LYOPHILIZED POWDER FOR CONCENTRATED SOLUTION	צורת מינון
I.V, ORAL	דרך מתן
VANCOMYCIN (AS HYDROCHLORIDE)	מרכיב פעיל
1000 MG/VIAL	חוזק
<p>Vancomycin hydrochloride is indicated for the treatment of severe or serious infections due to susceptible strains of methicillin - resistant (beta-lactam-resistant) staphylococci.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Antibiotic therapy is as an adjunct to appropriate surgical measures when staphylococcal infections are purulent and localized.</p> <p>For endocarditis due to Streptococcus viridans or Streptococcus bovis vancomycin hydrochloride has been shown to be effective in combination with an aminoglycoside.</p> <p>Vancomycin hydrochloride has been shown to be effective only in combination with an aminoglycoside for endocarditis due to enterococci (eg Enterococcus faecalis).</p> <p>Vancomycin hydrochloride has been shown to be effective for the treatment of diphtheroid endocarditis. In early-onset prosthetic valve endocarditis caused by Staphylococcus epidermidis</p>	התוויה

<p>or diptheroids 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 Pseudomembrannous colitis due to Staphylococcus enterocolitis and Clostridium difficile. Vancomycin hydrochloride is not effective orally when administered for other types of infection.</p>	
<p>סוף נובמבר 2023</p>	<p>תאריך תחילת הפסקת השייוק</p>
<p>סוף פברואר 2024</p>	<p>תאריך צפי לסיום הפסקת השייוק</p>
	<p>תאריך חזרה לשייוק (יש למלא משבצת זאת עם חזרת התכשיר לשייוק בפועל)</p>
<p>כן</p>	<p>הכללה בסל הבריאות: כן / לא</p>
<p>תכשיר מכרז. מיובא רק כאשר קיימת הזמנה מלקוח</p>	<p>סיבת הפסקת השייוק: סיבות תפעוליות / סיבות מסחריות</p>
<p>1000 MG/VIAL - 1 VIAL</p>	<p>גודל/י אריזה</p>
<p>אין</p>	<p>זמינות של גודל אריזה אחר או חוזק אחר של התכשיר</p>