ונקומיצין מיילן Vancomycin Mylan 500 mg
ונקומיצין מיילן Vancomycin Mylan 1 g
Lyophilized Powder for Concentrated Solution

- העלון לרופא עודכן במאי 2017.
- בהודעה זו מצוינים השינויים המהווים החמרה. בעלון שינויים נוספים שאינם החמרה.
- טקסט שהתווסף מסומן בקו תחתי, טקסט שהוסר מסומן בקו חוצה.

חומר פעיל: Vancomycin (as hydrochloride) 500mg or 1 g

ההתוויה המאושרת 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 fecalis).
Vancomycin hydrochloride has been shown to be effective for the treatment of diphtheroid endocareditis. In early-onset prosthetic valve endocarditis caused by Staphylococcus epidermidis 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 administration: 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.

העדכונים בעלון נעשו בסעיפים הבאים :

4.1 Therapeutic indications

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Oral ~~Therapy~~ administration:

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.

Vancomycin is ineffective in these diseases if given parenterally

4.4 Special warnings and precautions for use

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~~Nephrotoxicity:~~Some patients with inflammatory disorders of the intestinal mucosa may have significant systemic absorption of oral vancomycin ~~must be used with caution~~and, therefore, may be at risk for the development of adverse reactions associated with the parenteral administration of vancomycin. The risk is greater in patients with renal ~~failure as~~impairment. It should be noted that the ~~possibility~~total systemic and renal clearances of ~~developing toxic effects is much higher~~vancomycin are reduced in the ~~presence~~elderly.

4.6 ~~Fertility,~~ Pregnancy and lactation

~~Vancomycin should be cautiously given to breast-feeding mothers because of potential adverse reactions in the infant (disturbances in the intestinal flora with diarrhoea, colonisation with yeast-like fungi and possibly sensibilisation).~~

~~Considering the importance of this medicine for nursing mother, the decision should to stop breastfeeding should be considered.~~

Usage in pregnancy*:*

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It has been reported, however, that pregnant patients may require significantly increased doses of vancomycin to achieve therapeutic serum concentrations.

Usage in nursing mothers:

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It is unlikely that a nursing infant can absorb a significant amount of vancomycin from its gastro-intestinal tract.

Infusion-related events*:* During or soon after rapid infusion of vancomycin, patients may develop anaphylactoid reactions including hypotension, wheezing, dyspnoea, urticaria or pruritus. Rapid infusion may also cause flushing of the upper-body ('red-neck'syndrome) or pain and muscle spasm of the chest and back. These reactions usually resolve within 20 minutes but may persist for several hours. In animal studies, hypotension and bradycardia occurred in animals given large doses of vancomycin at high concentrations and rates. Such events are infrequent if vancomycin is given by slow infusion over 60 minutes. In studies of normal volunteers, infusion-related events did not occur when vancomycin was administered at a rate of 10mg/min or less.

Rapid bolus injection may give hypotension, bradycardia, cardiogenic shock and rarely cardiac arrest.

Nephrotoxicity*:* Rarely, renal failure, principally manifested by increased serum creatinine or blood urea concentrations, have been observed, especially in patients given large doses of intravenously administered vancomycin. Rare cases of interstitial nephritis have been reported. Most occurred in patients who were given aminoglycosides concomitantly or who had pre-existing kidney dysfunction. When vancomycin was discontinued, azotaemia resolved in most patients.

Ototoxicity*:* Hearing loss associated with intravenously administered vancomycin has been reported. Most of these patients had kidney dysfunction, pre-existing hearing loss, or concomitant

treatment with an ototoxic drug. Vertigo, dizziness and tinnitus have been reported rarely. Tinnitus, possibly preceding onset of deafness, may occur and should be regarded as an indication to discontinue treatment.
***Haematological**:* Reversible neutropenia, usually starting one week or more after onset of intravenous therapy or after a total dose of more than 25 g. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has rarely been reported. Reversible agranulocytosis (less than 500 granulocytes per mm3) has been reported rarely, although causality has not been established. Eosinophilia has been reported.
***Miscellaneous**:* Phlebitis, hypersensitivity reactions anaphylaxis, nausea, chills, drug fever, rashes (including exfoliative dermatitis) and rare cases of vasculitis. Vancomycin has been associated with the bullous eruption disorders, Stevens-Johnson syndrome, toxic epidermal necrolysis and linear IgA bullous dermatosis. If a bullous disorder is suspected, the drug should be discontinued and specialist dermatological assessment should be carried out.

4.9 Overdose

~~Toxicity due to overdose has been reported. 500 mg IV to a child, 2 year of age, resulted in lethal intoxication.~~
~~Administration of a total of 56 g during 10 days to an adult resulted in renal insufficiency. In certain high-risk conditions (e. g. in case of severe renal impairment) high serum levels and oto- and nephrotoxic effects can occur.~~

~~*Measures in case of overdose*~~
~~• A specific antidote~~Supportive care is ~~not known.~~
~~• Symptomatic treatment while maintaining renal function is required.~~
~~advised, with maintenance of~~ glomerular filtration. Vancomycin is poorly removed from the blood by haemodialysis or peritoneal dialysis. ~~Haemofiltration or~~ Haemoperfusion with ~~polysulfone resins have~~Amberlite resin XAD-4 has been ~~used~~reported to ~~reduce serum concentrations~~be of ~~vancomycin~~limited benefit.

6.2 Incompatibilities

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Vancomycin solutions must basically be administered separately unless chemicophysical tolerability with other infusion solutions has been proven.
Combination therapy
In the event of combination therapy with vancomycin and other antibiotics / chemotherapeutic agents, they must be administered separately.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות.
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