הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 8/3/2017

שם התכשיר באנגלית ומספר הרישום Vancomycin Mylan 500 mg – 123-63-30297

Vancomycin Mylan 1 g – 123-64-30298

שם בעל הרישום: Genmedix

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט נוכחי	**טקסט חדש**	**פרק בעלון**
… 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. Consideration should be given to official guidance on the appropriate use of antibacterial agents.	… 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	**4.1 Therapeutic indications**
… Nephrotoxicity: vancomycin must be used with caution in patients with renal failure as the possibility of developing toxic effects is much higher in the presence of prolonged high blood concentrations. In the treatment of these patients and in those who are receiving concomitant treatment with other nephrotoxic active substances (i.e. aminoglycosides), serial tests of renal function must be performed and the appropriate dose regimens adhered to in order to reduce the risk of nephrotoxicity to a minimum (see section 4.2).	… ~~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	**4.4 Special warnings and precautions for use**

מעוצב:גופן: (ברירת מחדל) lairA, 10 נק', לא מודגש, גופן עבור עברית ושפות אחרות: lairA, 10 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית), גרמנית (גרמניה)

מעוצב:גופן: 11 נק', גופן עבור עברית ושפות אחרות: semiT weN namoR, 11 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית), אנגלית (בריטניה), אל תבדוק איות או דקדוק

מעוצב:גופן: (ברירת מחדל) semiT weN namoR, 11 נק', גופן עבור עברית ושפות אחרות: semiT weN namoR, 11 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית), סמן

מעוצב:גופן: 11 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית), גרמנית (גרמניה), סמן

מעוצב:גופן: 11 נק', סמן

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מעוצב:גופן: 11 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית), גרמנית (גרמניה), סמן

מעוצב:גופן: 11 נק', סמן

מעוצב:גופן: (ברירת מחדל) lairA 10 נק', צבע גופן: שחור, גופן עבור עברית ושפות אחרות: namoR weN semiT 10 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית),

מעוצב:משמאל לימין, תבנית: נקי (לבן)

מעוצב:גופן: (ברירת מחדל) lairA 10 נק', צבע גופן: שחור, גופן עבור עברית ושפות אחרות: namoR weN semiT 10 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית),

מעוצב:גופן: (ברירת מחדל) lairA 10 נק', צבע גופן: שחור, גופן עבור עברית ושפות אחרות: namoR weN semiT 10 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית),

מעוצב:משמאל לימין, תבנית: נקי (לבן)

		~~presence~~elderly.	
… 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.		~~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.~~	**4.6 ~~Fertility,~~ Pregnancy and lactation**
		Usage in pregnancy: … It has been reported, however, that pregnant patients may require significantly increased doses of vancomycin to achieve therapeutic serum concentrations. ***Usage in nursing mothers:*** … It is unlikely that a nursing infant can absorb a significant amount of vancomycin from its gastro-intestinal tract.	
System Organ Class	**Frequency grouping**	***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	**4.8 Undesirable effects**
Blood and lymphatic system disorders	Rare - thrombocytopenia neutropenia, agranulocytosis, - eosinophilia.		
Immune system disorders	Rare anaphylactic reactions, - hypersensitivity reactions.		

Ear and labyrinth disorders	Uncommon - transient or permanent loss of hearing. Rare - tinnitus, - dizziness.	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.
Cardiac disorders	Very Rare - cardiac arrest.	
Vascular disorders	Common - decrease in blood pressure, thrombophlebitis. Rare - vasculitis.	
Respiratory, thoracic and mediastinal disorders	Common - dyspnoea, - stridor.	
Gastrointestinal disorders	Rare - nausea Very Rare - pseudomembranous enterocolitis after intravenous administration.	
Skin and subcutaneous tissue disorders	Common - exanthema and mucosal inflammation, - pruritus, - urticaria. Very Rare - exfoliative dermatitis, - Stevens-Johnson syndrome, - Lyell's syndrome,	

	- IgA induced bullous dermatitis.			
Renal and urinary disorders	Common - renal insufficiency manifested primarily by increased serum creatinine or serum urea concentrations. Rare - interstitial nephritis, - acute renal failure.			
General disorders and administration site conditions	Common - redness of the upper body and the face, - pain and spasm of the chest and back muscles. Rare - drug fever, - shivering.			
During or shortly after rapid infusion anaphylactic reactions may occur, including hypotension, dyspnea, urticaria or pruritus. The reactions abate when administration is stopped, generally between 20 minutes and 2 hours after having stopped administration. Ototoxicity has primarily been reported in patients given high doses, or concomitant treatment with other ototoxic medicinal products, or with pre-existing reduction in kidney function or hearing. After oral administration, as vancomycine could be absorbed in case of digestive lesion, the risk of the above mentioned undesirable effects described cannot be eliminated.				

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 is not known. • Symptomatic treatment while maintaining renal function is required. Vancomycin is poorly removed from the blood by haemodialysis or peritoneal dialysis. Haemofiltration or haemoperfusion with polysulfone resins have been used to reduce serum concentrations of vancomycin.	~~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.	**4.9 Overdose**
…	… *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.	**6.2 Incompatibilities**

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מעוצב:משמאל לימין, תבנית: נקי (לבן)

מעוצב:גופן: 11 נק', צבע גופן: שחור, גופן עבור עברית ושפות אחרות: semiT namoR weN, 11 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית),

מעוצב:שמאל, משמאל לימין, שנה רווח בין טקסט לטיני לאסיאתי, שנה רווח בין טקסט אסיאתי למספרים, תבנית: נקי (לבן)

מעוצב:גופן: 11 נק', צבע גופן: שחור, גופן עבור עברית ושפות אחרות: semiT namoR weN, 11 נק', (עברית ושפות אחרות) ערבית (ערב הסעודית),

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מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך 8/3/2017