VANCOMYCIN ALTIEX

500 mg & 1000 mg pulver til koncentrat til infusionsvæske, opløsning

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Vancomycin is an antibiotic that is used to treat severe infections of the lining or valves of the heart, lungs, bone or soft tissues (flesh) caused by bacteria which can resist other antibiotics called gram-positive micro-organisms. In the last few years, there has been a significant increase in resistance among these micro-organisms, with a marked epidemiological and clinical impact in daily clinical practice. For example, in the United States, approximately 60% of these infections in hospitals are caused by resistant strains, and percentages continue to rise. In Spanish hospitals, the prevalence of resistant strains remains high (ranged 25-75% depending on micro-organism type) and in the community, new resistant strains are emerging in patients without risk factors. The spread is being produced within hospitals, nursing homes, the community, countries and continents and is even being caused by the existence of resistance genes.

VI.2.2 Summary of treatment benefits

Published clinical trials have presented evidence of vancomycin effectiveness in the following treatments:

- In Staphylococcal infections, such as, infections of lining of valves of the heart, lungs, and soft tissue, the majority of the patients treated with vancomycin improved clinically.

- Endocarditis. Vancomycin showed effectiveness in endocarditis caused not only by Staphylococcus but also by Streptococcus antimicrobial agents.

- In the treatment of neutropenia with cancer patients, vancomycin was more effective compared to on the comparator treatment.

VI.2.3 Unknowns relating to treatment benefits

The benefits and safety of vancomycin have not been established in pregnant and breastfeeding women.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergic reactions to vancomycin	Allergic reactions reportedly occur in 5-10% of patients receiving vancomycin. Vancomycin may cause a serious or life-threatening allergic reaction that may affect the skin or other parts of the body such as liver or blood cells.	Not totally preventable. The patient must not receive vancomycin if they are allergic to this antibiotic. Likewise, if the patients are allergic to another antibiotic called teicoplanin, they can also be allergic to vancomycin. Before using the medication, patients should inform their doctors if they have had problems with this medicine in the past. Patients under vancomycin should contact their doctors or nurses at once if they get any of the following effects: swelling of the face or throat, difficulty in breathing, feeling faint, itchy skin or hives. In these cases the infusion of vancomycin must be halted.
Temporary or permanent loss of hearing, dizziness, a ringing or buzzing in your ears	Deafness, transitory or permanent, , can occur in patients with prior deafness, who have received excessive doses, or who receive treatment with a substance damaging to hearing.	Yes. Before using the medication, patients should inform their doctors if they had suffered from loss of hearing in the past. To reduce this risk, it is recommended to check vancomycin blood levels periodically and to perform periodic testing of hearing function.
Increased risk of kidney toxicity in patient with impaired or reduced kidney function	Kidney problems are common side effects for vancomycin. In patients who suffer from kidney failure or receive concomitant treatment with other substances toxic to the kidney the possibility of developing toxic effects is much higher. As the dose of vancomycin depend on the age and general health condition, checking renal function and blood levels is recommended and dose adjustment as appropriate in elderly patients and in patients with kidney problems.	Yes. Before using the medication, patients should inform their doctors if they have had kidney problems in the past. Doctors should perform tests to see if the kidneys are working properly and to check vancomycin blood levels periodically.
Events related to the administration procedure such as vein wall inflammation including blood clotting (phlebitis)	Phlebitis is a common side effect for vancomycin. Vancomycin is given by hospital staff, using an infusion, (a slow injection by means of a drip). Each infusion will be given slowly, usually lasting for at least one hour.	Yes. Slow infusion of this medicine may reduce this side effect.

Risk	What is known	Preventability
	During, or shortly after, rapid infusion low blood pressure, difficulty breathing, shock, itchy skin rash, redness or the skin of the upper body, pain and cramp in chest or back muscle can occur. Vancomycin should be given slowly (for more than 60 minutes) to avoid these reactions. Stopping the infusion usually results in a prompt cessation of the reactions. Injection site pain, inflammation of the vein wall and blood clotting can occur and is occasionally severe. Slow administration also reduces these side effects.	
Decrease in the number of a type of white blood cells in the blood (neutrophils)	Reversible neutropenia for vancomycin has been reported with a rare frequency.	Yes. A test to check white blood cells periodically may detect significant decreases.
Interaction of vancomycin with other drugs	Vancomycin may affect other medicines if taken at the same time: - Anaesthetics may increase side effects of vancomycin when are used during a general anaesthetic. - Aminoglycosides (such as gentamycin, amphotericin A, neomycin, amikacin, tobramycin, etc) can increase ototoxic and nephrotoxic side effects of vancomycin. - Muscle relaxants (such as suxamethonium, vecuronium) increase their effects when used with vancomycin during a general anaesthetic.	Yes. Before using the medication, patients should inform their doctors if they are taking or have been recently taken any other medicines, including medicines obtained without prescription.

Important potential risks

Risk	What is known
Infections and infestations (Superinfection)	Prolonged use of vancomycin may result in the overgrowth of resistant organisms.
Infammation of the colon (Pseudomembraneous colitis)	It is important to consider this diagnosis who present with diarrhoea subsequent to the administration of vancomycin, as there have been some reports of patients experiencing this condition after intravenous administration of vancomycin.

Missing information

Risk	What is known
Use in pregnant women	Studies performed in rats and rabbits showed no effect direct or indirect effects. There are no adequate data for the use of vancomycin in pregnant women.
Use in breastfeeding women	It is known that vancomycin passes into breast milk. There are no adequate data for the use of vancomycin in breastfeeding women.
Use in patients with liver damage	There are limited data for the use of vancomycin in patients with liver damage. Patients with severe liver damage, special test will be carried out and the dose will be adjusted.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures. Routine pharmacovigilance should be sufficient for post-marketing safety monitoring of the risks.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

SUMMARY OF CHANGES TO THE RMP		
DATE	**VERSION NUMBER**	**CHANGES**
March 2015	01 (not approved)	As per Agency's preliminary assessment report, the following changes to the RMP have been addressed: 1. The brand name of the product have been changed. 2. The safety concern *Pseudomembraneous colitis has been included.* 3. The risks have been listed in terms of their preferred terms, the SOC category have been removed. 4. References to wording from Section 2.5.5 Overview of Safety for the risks of neutropenia and drug interactions have been removed. 5. Tables V.1 and V.3 have been updated to align with modificactions made to summary table of safety concerns.

		6. In columna 1 of table VI.2.4, the medical term for each of the risks have been added in parentheses after the layman term. 7. Remove the references to oral administration from Part I: Product Overview (Indications in the EEA and Posology and route of administration in EEA) have been removed. 8. In the Part VII-Annexes, the Danish SPC has been included.
Januray 2016	02 (not approved)	As per SPC assessment performed by the Danish Regulatory Authority, the following changes to the RMP have been addressed: 1. Information on general posology and route of administration has been modified, including the elderly. 2. DRESS Syndorme has been deleted as an identified risk as is not included in the new proposed SPC. 3. Name of some identified and potential risk have been slightly modified according tho the reference SPC and the list of identified and potential risks proposed in the Heads of Medicines Agency (HMA) webpage. 4. New or modified information in the new proposed SPC has been included in each relevant section of the RMP.
March 2016	03 (not approved)	As per Agency's second assessment report (11 February 2016), the following changes to the RMP have been addressed: 1. Identified risk "Increased risk for patients with decreased/impaired renal function" has been reworded to "Increased risk of nephrotoxicity in patients with decreased/impaired renal function" as suggested. Relevant sections of the RMP have been reviewed and changed in order to reflect this change. 2. Update the RMP with last version of the product's SPC and PIL.