EMA recommends changes to prescribing information for vancomycin antibiotics

10/07/2017 | P11/2017

Information on Vancomycin

- Vancomycin is an antibiotic used in the treatment of serious infections caused by Gram-positive bacteria.
- It is given by infusion (drip) into a vein to treat serious infections due to Gram-positive bacteria such as meticillin-resistant Staphylococcus aureus (MRSA) that are resistant to other antibiotics, or in patients in whom other antibiotics cannot be used.
- It can also be used for perioperative prophylaxis in patients at risk of developing bacterial endocarditis and for the treatment of peritoneal dialysis-associated peritonitis.

In Malta vancomycin-containing products are authorised through various licensing procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Vancomycin 500 mg	Vancomycin Norma	Powder for solution for infusion	POM	AA1025/01201	Norma Hellas S.A.
Vancomycin Hydrochloride 500 mg/mL	Vancomycin 500mg Powder for Solution for Infusion	Powder for solution for infusion	POM	AA154/07001	Wockhardt UK Limited
Vancomycin Hydrochloride 500 mg/mL	Vancomycin 500mg	Powder for solution for infusion	POM	MA157/01401	Hospira UK Limited
Vancomycin 125 mg	Vancocin Matrigel 125mg	Hard capsules	POM	AA565/04601	Central Procurement & Supplies Unit
Vancomycin Hydrochloride 1 g/mL	Voxin Powder for Solution for Infusion 1g/vial	Powder for solution for infusion	POM	AA721/00501	Vianex S.A
Vancomycin 125 mg	Vancomycin Capsules Hard 125mg	Hard capsules	POM	AA729/18401	Cherubino Limited

Changes aim to ensure appropriate use in context of fight against antimicrobial resistance

The European Medicines Agency (EMA) has recommended changes to prescribing information for vancomycin to ensure appropriate use in the treatment of serious infections. This follows a review of the available data on vancomycin medicines given by infusion (drip), injection and taken by mouth. The review is part of the EMA strategy to update the product information of old antibacterial agents in the context of the fight against antimicrobial resistance.

- Vancomycin can continue to be used for the treatment of serious infections caused by certain bacteria including MRSA (meticillin-resistant *Staphylococcus aureus*) in patients of all ages.
- Vancomycin can also be used to prevent bacterial endocarditis (an infection in the heart) in patients undergoing surgery and patients undergoing peritoneal dialysis.
- Oral administration should be limited to the treatment of *Clostridium Difficile*.
- Vancomycin should no longer be used in the treatment of *Staphylococcal Enterocolitis* and to clear the gut of bacteria in patient with a weakened immune system since adequately supportive data is lacking.
- The starting dose of vancomycin by infusion should be calculated according to the age and weight of the patient.

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP). The CHMP's opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

In Malta

For Healthcare Professionals

Recommendations are based on the EMA's review of the available pharmacological and clinical data for vancomycin. The recommendations concern vancomycin infusions and capsules.

Vancomycin solution for infusion:

- Vancomycin solution for infusion can be used in patients of all ages for the treatment of complicated soft-tissue infections, bone and joint infections, community/hospital-acquired pneumonia (including ventilator-associated pneumonia), infective endocarditis, acute bacterial meningitis, and bacteraemia associated with the above infections. It can also be used for perioperative prophylaxis in patients at risk of developing bacterial endocarditis and for the treatment of peritoneal dialysis-associated peritonitis.
- The recommended starting dose of vancomycin solution for infusion should be based on the age and weight of the patient. Available data showed that the previously recommended

daily dose often resulted in sub-optimal vancomycin serum concentrations. Any subsequent dose adjustments should be based on serum concentrations.

- Vancomycin parenteral formulations authorised for oral use can be used by mouth in patients of all ages for the treatment of Clostridium difficile infection (CDI).
- Vancomycin parenteral formulations authorised for intraperitoneal use can be used in patients of all ages for the treatment of peritoneal dialysis-associated peritonitis.

Vancomycin capsules:

- Oral vancomycin should no longer be used in the treatment of staphylococcal enterocolitis and for the decontamination of the GI tract in immune-compromised patients since its use is not adequately supported by data.
- Vancomycin capsules can be used in patients aged 12 years and older for the treatment of CDI. For younger children, the use of age-appropriate formulations is recommended.
- The maximum dose should not exceed 2 g per day.
- Serum concentration of vancomycin after oral administration should be closely monitored in patients with inflammatory intestinal disorders.

Information for Patients

- Vancomycin is an antibiotic used for serious infections, often caused by bacteria that have become resistant to other treatments. It is given as an infusion (drip) into a vein, by injection in the abdomen (belly) or it can also be taken by mouth (as capsules or liquid) to treat an infection of the lining of the gut caused by bacteria called *Clostridium difficile*.
- The available information on vancomycin has been reviewed and recommendations have been made on its safe use and appropriate dosage; the product information vancomycin containing products will be changed accordingly.

For more information refer to the EMA press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on vancomycin containing products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: **http://www.medicinesauthority.gov.mt/adrportal**) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to **postlicensing.medicinesauthority@gov.mt** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

Postage will be paid
by the Licensee

No postage stamp
necessary if posted
in Malta and Gozo

BUSINESS REPLY SERVICE
Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000