Information on Vancomycin

- Vancomycin is a glycopeptides antibiotic and 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 is also given by mouth to treat Clostridium difficile-associated diarrhoea, an infection that can develop in hospital patients treated with other antibiotics.
- Vancomycin-containing medicines have been authorised nationally in the EU for many years, as Vancocin and a variety of other names.

In Malta the following products are authorised through national procedures:

Active ingredients	Product name	Pharmaceutical form	Classif-cation	Authorisation number	Mah/license holder
Vancomycin 500mg/vial	Vancomycin Norma	Powder for solution for infusion	POM	AA1025/01201	Norma Hellas S.A.
Vancomycin 500mg	Vancomycin Wockhardt	Powder for solution for infusion	POM	AA154/07001	Wockhardt UK Limited
Vancomycin 500mg	Vancomycin hospira	Powder for concentrate for solution for infusion	POM	MA157/01401	Hospira UK Limited
Vancomycin 125mg	Vancocin Matrigel capsules	Hard capsule	POM	AA729/14501	Cherubino Limited
Vancomycin 125mg	Vancocin Matrigel capsules	Hard capsule	POM	AA565/04601	Central Procurement & Supplies Unit
Vancomycin 1g/vial	Voxin	Powder for solution for infusion	POM	AA721/00501	Vianex S.A

Information about the review of vancomycin containing medicines

The European Medicines Agency (EMA) has started a review of medicines containing the antibiotic vancomycin as part of its strategy to update product information of older antibacterial agents in the context of the fight against antimicrobial resistance.

- The revision of product information for critically important antibiotics is considered an important way of promoting appropriate use.
- The aim is to ensure that effective and safe antibiotics remain available to EU patients.
- Vancomycin is an important therapeutic option to treat serious infections resistant to other antibiotics that have been caused by a group of bacteria known as Gram-positive organisms.
- Due to a growing problem of infections that are resistant to multiple antibiotics including vancomycin, it is considered of high relevance that the way this antibiotic is used in treating infections is re-assessed and that the product information for vancomycin-containing products is updated in light of available data.

The EMA will now review all available information on the benefits and risks of vancomycin and will consider whether any changes to its approved uses in the various Member States are required. For more information on review of vancomycin please refer to the European Medicines Agency's press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on vancomycin-containing medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending to **http://www.medicinesauthority.gov.mt/adrportal** or online at http://www.medicinesauthority.gov.mt/adrportal or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

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.

203, Level 3, Rue D'Argens, Il-Gżira, GZR 1368, Malta

info.medicinesauthority@gov.mt | (+356) 23 439 000

www.medicinesauthority.gov.mt

The Medicines Authority thanks you for your 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. Your feedback may be returned by folding this page address side up, stapling the ends and then posting (no stamp required)

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Pharmacovigilance Section

Post-licensing Directorate

Medicines Authority

203, Level 3

Rue D'Argens

Gzira GZR 1368