



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Review of vancomycin-containing medicines started

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.¹ 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. Because of 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.

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.

More about the medicine

Vancomycin is one of a group of antibiotics known as glycopeptides. It is given by infusion (drip) into a vein to treat serious infections due to Gram-positive bacteria such as methicillin-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.

1

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000439.jsp&mid=WC0b01ac058002d4e9

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More about the procedure

The review of vancomycin-containing medicines has been initiated at the request of the Spanish medicines agency (AEMPS), under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

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