



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2017
EMA/306160/2017

EMA recommends changes to prescribing information for vancomycin antibiotics

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 the antibiotic vancomycin to ensure appropriate use in the treatment of serious infections caused by Gram-positive bacteria.

Vancomycin has been used since the 1950s and to this day it remains an important therapeutic option for the treatment of serious infections. The Agency's Committee for Medicinal Products for Human Use (CHMP) reviewed the available data on vancomycin medicines given by infusion (drip) and injection and taken by mouth as part of its strategy to update the product information of old antibacterial agents in the context of the fight against antimicrobial resistance¹.

The CHMP concluded that infusion of 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 to treat infections in patients undergoing a procedure called peritoneal dialysis. When taken by mouth, use should be limited to the treatment of *Clostridium difficile* infections (CDI).

Because the available data do not adequately support the use of vancomycin in the treatment of staphylococcal enterocolitis (inflammation of the gut caused by *S. aureus*) and its use to clear the gut of bacteria in patients with a weakened immune (defence) system, the CHMP concluded that vancomycin should no longer be used for these indications.

In addition, the Committee reviewed the recommended dosage for vancomycin for the various indications and patient groups, and concluded that the starting dose of vancomycin by infusion should be calculated according to the age and weight of the patient. The updated recommendations are based on data which showed that the previously recommended dose often resulted in less than optimal levels of vancomycin in the blood, reducing the effectiveness of the antibiotic.

1

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000439.jsp&mid=WC0b01ac0580a7815d

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555

Send a question via our website www.ema.europa.eu/contact

An agency of the European Union



The CHMP opinion will now be forwarded to the European Commission, which will issue a final decision valid throughout the EU in due course.

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 or by injection in the abdomen (belly). 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 for medicines containing vancomycin will be updated to take these recommendations into account.
- Patients who have any questions about their treatment should talk to their doctor or pharmacist.

Information for healthcare professionals

The Agency's recommendations are based on a review of the available pharmacological and clinical data for vancomycin. The product information for vancomycin is being updated to reflect the following:

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- and 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 to achieve the target therapeutic 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

- The available data do not adequately support the use of oral vancomycin in the treatment of staphylococcal enterocolitis and for the decontamination of the GI tract in immunocompromised patients. Therefore, oral vancomycin should no longer be used in these indications.
- 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.

- In patients with inflammatory intestinal disorders, the serum concentration of vancomycin after oral administration should be closely monitored.

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 can also be used for perioperative prophylaxis in patients at risk of developing bacterial endocarditis and for the treatment of peritoneal dialysis-associated peritonitis.

Vancomycin is also given by mouth to treat infections caused by *Clostridium difficile*, which mostly 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.

More about the procedure

The review of vancomycin-containing medicines was initiated on 1 April 2016 at the request of the Spanish medicines agency (AEMPS), under [Article 31 of Directive 2001/83/EC](#).

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