COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Vancomycine Sandoz 500 mg and 1000 mg powder powder for solution for infusion

(vancomycin hydrochloride)

NL/H/4445/001/DC

Date: 17 July 2018

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Active substance: vancomycin hydrochloride

This is a summary of the public assessment report (PAR) for Vancomycine Sandoz. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Vancomycine Sandoz.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Vancomycine Sandoz and what is it used for?
Vancomycine Sandoz is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Vancocin.

The medicine is used to treat:

- Serious infections caused by vancomycin-sensitive bacteria which are resistant (insensitive) to many other antibiotics
- Patients allergic to penicillins and cephalosporins

It can also be given before some surgical procedures to prevent infections.

How does this medicine work?
Vancomycin belongs to a group of glycopeptide antibiotics which eliminate bacteria that cause many kinds of infections, including pneumonia and skin, bone and heart valve infections.

How is this medicine used?
The pharmaceutical form of Vancomycine Sandoz is a powder for solution. Before use, it will be dissolved and diluted with an intravenous fluid that will be given slowly by a drip into a vein by a doctor or nurse. The doctor will decide how much of this medicine should be received each day and how long the treatment will last.

The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
No additional studies were needed as Vancomycine Sandoz is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Vancocin.

What are the possible side effects of this medicine?
Because Vancomycine Sandoz is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Vancocin, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Vancomycine Sandoz, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Vancomycine Sandoz was granted on 1 February 2010.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Vancomycine Sandoz, read the package leaflet (http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con065756.pdf) or contact your doctor or pharmacist.

This summary was last updated in July 2018.