Summary Public Assessment Report

Generics

Cefepime-MIP 1 g and 2 g, powder for solution for injection or infusion

(cefepime)

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Cefepime-MIP 1 g and 2 g, powder for solution for injection or infusion
Active substance: cefepime

This is a summary of the public assessment report (PAR) for Cefepime-MIP. 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 Cefepime-MIP.

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

What is Cefepime-MIP and what is it used for?
Cefepime-MIP is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Maxipime 1 g and 2 g powder for solution for injection or infusion.

Cefepim-MIP is an antibiotic used in adults and children.

In adults and children over 12 years of age, it can be used for:
- Infections of the lung (pneumonia)
- Complicated (severe) infections of the urinary tract
- Complicated (severe) infections in the abdominal cavity
- Inflammation of the lining of the abdominal cavity (*peritonitis*) associated with dialysis in patients on continuous ambulatory peritoneal dialysis (CAPD)

In adults:
- Acute infections of the gallbladder

In children aged 2 months up to 12 years and with a body weight below 40 kg including:
- Complicated (severe) infections of the urinary tract
- Infections of the lung (pneumonia)
- Infections of the membranes covering the brain (*bacterial meningitis*)

Cefepime is also used in adults and in children older than 2 months
- in the treatment of attack of fever of unknown reason in patients with diminished resistance (if the fever is suspected to be due to a bacterial infection in patients with medium-severe to severe *neutropenia*). If necessary, a combination with another antibiotic sould be given.
- in the treatment of blood poisoning (*bacteraemia*).

How does this medicine work?
The active substance cefepime works by killing bacteria that cause infections. It belongs to a group of medicines called fourth generation cephalosporins.

How is this medicine used?
The pharmaceutical form of Cefepime-MIP is a powder for solution for injection or infusion. The medicine is usually given by a doctor or nurse. It can be given as a drip (intravenous infusion) or as an injection directly into a vein. 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 Cefepim-MIP is a generic medicine that is given by infusion or intravenous injection and contains the same active substance as the reference medicine, Maxipime.

What are the possible side effects of this medicine?
Because Cefepim-MIP 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 have comparable quality to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Maxipime, 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 Cefepim-MIP, 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 Cefepime-MIP 1 g and 2 g, powder for solution for injection or infusion was granted on 18 February 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human.
For more information about treatment with Cefepim-MIP, read the package leaflet (http://mri.medagencies.org/download/NL_H_2986_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in July 2015.