

# **Summary Public Assessment Report**

## **Generics**

### **Ceftazidim MIP (Ceftazidime pentahydrate)**

**NO/H/0243/001-002/DC**

**Date: 10.04.15**

# Summary Public Assessment Report

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### **Ceftazidim MIP**

ceftazidime pentahydrate 1g, powder for solution for injection/infusion (IM/IV)

ceftazidime pentahydrate 2g, powder for solution for injection/infusion (IV)

This is a summary of the public assessment report (PAR) for Ceftazidim MIP. It explains how Ceftazidim MIP 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 Ceftazidim MIP.

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

### **What is Ceftazidim MIP and what is it used for?**

Ceftazidim MIP is a 'generic medicine'. This means that Ceftazidim MIP is similar to a 'reference medicine' already authorised in the European Union (EU) called Fortum.

Ceftazidim MIP is an antibiotic used in the treatment of infections in adults and children.

Ceftazidim MIP is used to treat severe bacterial infections of:

- the lungs or chest
- the lungs and bronchi in patients suffering from cystic fibrosis
- the brain (*meningitis*)
- the ear
- the urinary tract
- the skin and soft tissues
- the abdomen and abdominal wall (*peritonitis*)
- the bones and joints.

Ceftazidim MIP can also be used:

- to prevent infections during prostate surgery in men
- to treat patients with low white blood cell counts (*neutropenia*) who have a fever due to a bacterial infection.

### **How does Ceftazidim MIP work?**

Ceftazidime belongs to a group of medicines called *cephalosporins*. It inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

### **How is Ceftazidim MIP used?**

The pharmaceutical form of Ceftazidim MIP is powder for solution for injection/infusion and the route of administration is intramuscular (1 g) and intravenous (1 g and 2 g).

The correct dose of Ceftazidim MIP depends on: the severity and type of infection; co-medication with other antibiotics; weight and age; renal function.

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

The medicine can only be obtained with a prescription.

### **What benefits of Ceftazidim MIP have been shown in studies?**

No additional studies were needed as Ceftazidim MIP is a generic medicine that is given by injection/infusion and contains the same active substance as the reference medicine Fortum.

### **What are the possible side effects of Ceftazidim MIP?**

Because Ceftazidim 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 restrictions, see the package leaflet.

### **Why is Ceftazidim MIP approved?**

It was concluded that, in accordance with EU requirements, Ceftazidim MIP has been shown to be comparable to Fortum. Therefore, the Norwegian Medicines Agency decided that, as for the reference medicine called Fortum, 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 Ceftazidim MIP?**

A risk management plan has been developed to ensure that Ceftazidim MIP 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 Ceftazidim 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 Ceftazidim MIP**

The marketing authorisation for Ceftazidim MIP was granted on 12.02.2015.

The full PAR for Ceftazidim MIP can be found on the website <http://mri.medagencies.org/Human/>. For more information about treatment with Ceftazidim MIP, read the package leaflet (link above) or contact your doctor or pharmacist.

This summary was last updated in 10-04-2015.