

**Summary Public Assessment Report**

**Generics**

**Levofloxacin Sandoz infuus 5 mg/ml,  
solution for infusion**

**(levofloxacin)**

**NL/H/3156/001/DC**

**Date: 8 May 2016**

## Summary Public Assessment Report

### Generics

Levofloxacin Sandoz infuus 5 mg/ml, solution for infusion

Active substance: levofloxacin

This is a summary of the public assessment report (PAR) for Levofloxacin Sandoz infuus 5 mg/ml, solution for infusion. 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 Levofloxacin Sandoz infuus.

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

#### **What is Levofloxacin Sandoz infuus and what is it used for?**

Levofloxacin Sandoz infuus is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Tavanic IV 5 mg/ml, solution for infusion.

Levofloxacin is used to treat infections of the:

- Lungs, for people with pneumonia
- Urinary tract, including the kidney or bladder
- Prostate gland, when there is a long lasting infection
- Skin and tissues underneath the skin, including muscles. These are sometimes called 'soft tissues'.

In some special situations the product may be used to lessen the chances of getting a pulmonary disease named anthrax, or to prevent worsening of the disease after exposure to the bacteria causing anthrax.

#### **How does this medicine work?**

Levofloxacin belongs to a group of medicines known as quinolone antibiotics, which work by killing the bacteria that cause infections in the body.

#### **How is this medicine used?**

The pharmaceutical form of Levofloxacin Sandoz infuus is solution for infusion and the route of administration is intravenous infusion. The dose depends on the type of the infection and the location of the infection in the body.

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 Levofloxacin Sandoz infuus is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Tavanic IV.

#### **What are the possible side effects of this medicine?**

Because Levofloxacin Sandoz infuus 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 and to be comparable to the reference medicine. Therefore, the Medicines

Evaluation Board of the Netherlands decided that, as for Tavanic IV, 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 Levofloxacin Sandoz infuus, 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.

**Other information about this medicine**

In the Netherlands, the marketing authorisation for Levofloxacin Sandoz infuus 5 mg/ml, solution for infusion was granted on 17 November 2015.

The full PAR for this medicine can be found on the website <http://mri.medagencies.org/Human>. For more information about treatment with Levofloxacin Sandoz infuus, read the package leaflet ([http://db.cbg-meb.nl/Bijsluiters/h115544\\_piluk.pdf](http://db.cbg-meb.nl/Bijsluiters/h115544_piluk.pdf)) or contact your doctor or pharmacist.

This summary was last updated in May 2016.