# Summary Public Assessment Report

## Generics

# Linezolid Sandoz 600 mg, film-coated tablets (linezolid)

## NL/H/2965/001/DC

## Date: 8 January 2015

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Linezolid Sandoz 600 mg, film-coated tablets
Active substance: linezolid

This is a summary of the public assessment report (PAR) for Linezolid Sandoz 600 mg, film-coated tablets. 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 Linezolid Sandoz.

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

**What is Linezolid Sandoz 600 mg and what is it used for?**
Linezolid Sandoz 600 mg is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Zyvox or Zyvoxid 600 mg film-coated tablets.

Linezolid is an antibiotic. It is used to treat pneumonia and some infections in the skin or under the skin in adults.

**How does this medicine work?**
Linezolid is an antibiotic that works by stopping the growth of certain bacteria (germs) that cause infections. It prevents bacteria from making proteins. Bacteria cannot develop without proteins.

**How is this medicine used?**
The pharmaceutical form of Linezolid Sandoz is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription. The usual dose is one tablet (600 mg linezolid) twice daily (every twelve hours). The tablet should be swallowed whole with some water. A course of treatment usually lasts 10 to 14 days but can last up to 28 days.

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?**
Because Linezolid Sandoz 600 mg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Zyvoxid 600 mg film-coated tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects of this medicine?**
Because Linezolid Sandoz is a generic medicine and is bioequivalent to the reference 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 bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Zyvoxid, 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 Linezolid 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 Linezolid Sandoz 600 mg, film-coated tablets was granted on 5 August 2014.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Linezolid Sandoz, read the package leaflet (http://db.cbg-meb.nl/Bijsluiters/h113822_piluk.pdf) or contact your doctor or pharmacist.

This summary was last updated in January 2015.