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Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Summary Public Assessment Report

Generics

Linezolida Kabi
2 mg/ml, Solution for infusion
(linezolid)

PT/H/1090/001/DC

Date: 27-03-2015

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Generics

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Linezolid, 2 mg/ml, Solution for infusion

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

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

What is Linezolida Kabi and what is it used for?

Linezolida Kabi is a 'generic medicine'. This means that Linezolida Kabi is similar to a 'reference medicine' already authorised in the European Union (EU) called Zyvox.
Linezolida Kabi contains linezolid and is used to treat pneumonia and some infections in the skin or under the skin.

How does Linezolida Kabi work?

Linezolida Kabi is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria that cause infections.

How is Linezolida Kabi used?

The pharmaceutical form of Linezolida Kabi is Solution for infusion and the route of administration is intravenous.

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 Linezolida Kabi have been shown in studies?

No additional studies were needed as Linezolida Kabi is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Zyvox.

What are the possible side effects of Linezolida Kabi?

Because Linezolida Kabi 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 Linezolida Kabi approved?

It was concluded that, in accordance with EU requirements, Linezolida Kabi has been shown to have comparable quality and to be comparable to Zyvox. Therefore, Infarmed decided that,

as for Zyvox, 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 Linezolida Kabi?
A risk management plan has been developed to ensure that Linezolida Kabi 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 Linezolida Kabi, 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 Linezolida Kabi

The marketing authorisation for Linezolida Kabi was granted on 27-03-2015.

The full PAR for Linezolida Kabi can be found on the website www.infarmed.pt/infomed. For more information about treatment with Linezolida Kabi, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in MM-YYYY.

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Public Assessment Report

Scientific discussion

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This module reflects the scientific discussion for the approval of Linezolida Kabi. The procedure was finalised at 01-10-2014. For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Linezolida Kabi, 2 mg/ml, Solution for infusion, from Fresenius Kabi Pharma Portugal, Lda..
The product is indicated in adults for the treatment of nosocomial pneumonia and community acquired pneumonia
A comprehensive description of the indications and posology is given in the SmPC.

The marketing authorisation has been granted pursuant to Article 10.1 of Directive 2001/83/EC.
The reference medicinal product is Zyvox 2 mg/ml Solution for Infusion by Pharmacia Limited, authorized since 05-01-2001.

II. QUALITY ASPECTS

II.1 Introduction

Linezolida Kabi is a solution for infusion, isotonic, clear, practically free from particles, colourless to yellow.

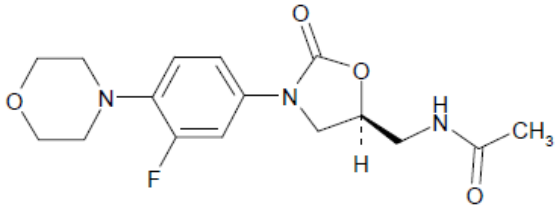
1 ml solution for infusion contains 2 mg linezolid.
Each 300 ml infusion bags contain 600 mg linezolid.

The excipients are glucose monohydrate, sodium citrate, citric acid anhydrous, hydrochloric acid or sodium hydroxide and water for injections.

Single use, ready-to-use, latex-free, multilayered polyolefine film infusion Freeflex bags sealed inside a foil laminate overwrap (polyester/polypropylene aluminium film).

The bag holds 300 ml solution and is packaged in a box.
Each box contains 10, 30 or 50 infusion bags.

II.2 2.2 Drug Substance



INN: Linezolid
Molecular formula: $C_{16}H_{20}FN_3O_4$.
Molecular weight: 337.35.
Description: A white to off white crystalline powder.

Solubility: Linezolid (Form-III) is freely soluble in Chloroform, sparingly soluble in Methanol.

The chemical-pharmaceutical documentation and Quality Overall Summary in relation to linezolid are of sufficient quality in view of the present European regulatory requirements.

II.3 Medicinal Product

The development of the product has been described, the choice of excipients is justified and their functions explained.
The product specifications cover appropriate parameters for this dosage form. The batch analysis results show that the finished products meet the specifications proposed.
The conditions used in the stability studies are according to the ICH stability guideline. The control tests and specifications for drug product are adequately drawn up.
The proposed shelf-life of 24 months before opening is considered acceptable. The drug product should be stored in the original package in order to protect from light.
Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C and 25°C.

III. NON-CLINICAL ASPECTS

Pharmacodynamic, pharmacokinetic and toxicological properties of linezolid are well known. As linezolid is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)
An Environmental Risk Assessment has not been performed as the product is intended for generic substitution. A disposal advice was added to the SmPC.

IV. CLINICAL ASPECTS

Pharmacovigilance system
According with Article 8(3)(ia) of Directive 2001/83/EC the applicant has provided following elements in module 1.8.1 of the dossier:
• proof that the applicant has at his disposal a qualified person responsible for pharmacovigilance;
• the Member States in which the qualified person resides and carries out his/her tasks;
• the contact details of the qualified person;
• a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Title IX;
• a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.
The QPPV CV is adequate and the statement is in agreement with the legislation.

Risk Management Plan
The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Based on the review of the data on safety and efficacy, the RMS considers that the application for Linezolida Kabi, 2 mg/ml, Solution for infusion, is approvable.