Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

Decentralised Procedure

Linezolid 600 mg film-coated tablets

(Linezolid)

Procedure No: UK/H/6622/001/DC

UK Licence Number: PL 35646/0067

Alkem Pharma GmbH

LAY SUMMARY

Linezolid 600 mg film-coated tablets

(linezolid)

This is a summary of the Public Assessment Report (PAR) for Linezolid 600 mg film-coated tablets (PL 35646/0067; UK/H/6622/001/DC). It explains how Linezolid 600 mg film-coated tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

The product will be referred to as 'Linezolid tablets' throughout the remainder of this PAR

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

What are Linezolid tablets and what are they used for?
Linezolid tablets is a 'generic medicine'. This means that Linezolid tablets is similar to a 'reference medicine' already authorised in the European Union (EU) called Zyvox 600 mg film-coated tablets (PL 00032/0261; Pharmacia Limited, UK).

This medicine is used to treat pneumonia and some infections in the skin or under the skin. The patient's doctor will have decided if Linezolid tablets are suitable to treat their infection.

How do Linezolid tablets work?
Linezolid tablets contain the active substance linezolid which is an antibiotic of the oxazolidinones group. It works by stopping the growth of certain bacteria (germs) that cause infections.

How are Linezolid tablets used?
The pharmaceutical form of this medicine is a film-coated tablet and the route of administration is oral (by mouth).

Adults
The patient should always take this medicine exactly as described in the package leaflet or as their doctor, pharmacist or nurse has told them. The patient should check with their doctor, pharmacist or nurse if they are not sure.

The recommended dose is one film-coated tablet (600 mg linezolid) twice daily (every twelve hours). Swallow the tablet whole with some water.

If the patient is on kidney dialysis, they should take this medicine after their dialysis treatment.

A course of treatment usually lasts 10 to 14 days, but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. The patient's doctor will decide how long they should be treated.

Whilst the patient is taking Linezolid tablets, their doctor should perform regular blood tests to monitor the patient's blood count.

The patient's doctor should monitor their eyesight if the patient takes Linezolid tablets for more than 28 days.

Use in children and adolescents
Linezolid tablets are not normally used to treat children and adolescents (under 18 years old).

Please read section 3 of the package leaflet for detailed dosing recommendations, the route of administration, and the duration of treatment.

For further information on how Linezolid tablets are used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

What benefits of Linezolid tablets have been shown in studies?
No additional studies were needed as the company submitted data to support a BCS-based biowaiver in line with the regulatory requirements of 'Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**).'

What are the possible side effects of Linezolid tablets?
Linezolid tablets are a generic medicine and are bioequivalent to the reference medicine Zyvox 600 mg film-coated tablets (PL 00032/0261; Pharmacia Limited, UK) so the benefits and possible side effects are taken as being the same as for the reference medicine.

For the full list of restrictions, see the package leaflet.

For the full list of all side effects reported with Linezolid tablets, see section 4 of the package leaflet available on the MHRA website.

Why was Linezolid tablets approved?
It was concluded that, in accordance with EU requirements, Linezolid tablets have been shown to have comparable quality and to be bioequivalent to Zyvox 600 mg film-coated tablets (PL 00032/0261; Pharmacia Limited, UK). Therefore, the MHRA decided that, as for Zyvox 600 mg film-coated tablets (PL 00032/0261; Pharmacia Limited, UK), the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Linezolid tablets?
A risk management plan (RMP) has been developed to ensure that Linezolid tablets are used as safely as possible. Based on this plan, safety information has been included in the SmPC and the package leaflet for Linezolid tablets 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.

Other information about Linezolid tablets
Germany and the UK agreed to grant a Marketing Authorisation for Linezolid tablets on 02 October 2018. A Marketing Authorisation was granted in the UK on 22 October 2018.

The full PAR for Linezolid tablets follows this summary.

This summary was last updated in November 2018.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Member States considered that the application for Linezolid tablets (PL 35646/0067; UK/H/6622/001/DC), is approvable. Linezolid tablets is a Prescription-Only Medicine (POM) indicated in adults for:

Nosocomial pneumonia and community acquired pneumonia
Linezolid tablets are indicated in adults for the treatment of community acquired pneumonia and nosocomial pneumonia when known or suspected to be caused by susceptible Gram positive bacteria. In determining whether Linezolid tablets is an appropriate treatment, the results of microbiological tests or information on the prevalence of resistance to antibacterial agents among Gram positive bacteria should be taken into consideration. (See section 5.1 of the SmPC for the appropriate organisms).

Linezolid is not active against infections caused by Gram negative pathogens. Specific therapy against Gram negative organisms must be initiated concomitantly if a Gram negative pathogen is documented or suspected.

Complicated skin and soft tissue infections
Linezolid tablets are indicated in adults for the treatment of complicated skin and soft tissue infections **only** when microbiological testing has established that the infection is known to be caused by susceptible Gram positive bacteria.

Linezolid is not active against infections caused by Gram negative pathogens. Linezolid should only be used in patients with complicated skin and soft tissue infections with known or possible co-infection with Gram negative organisms if there are no alternative treatment options available (see section 4.4 of the SmPC). In these circumstances treatment against Gram negative organisms must be initiated concomitantly.

Linezolid should only be initiated in a hospital environment and after consultation with a relevant specialist such as a microbiologist or infectious diseases specialist.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The application was submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State and Germany as Concerned Member State (CMS).

The application was submitted under Article 10(1) of Directive 2001/83/EC, as amended, as a generic application. The reference product is Zyvox 600 mg film-coated tablets (PL 00032/0261) which was granted a Marketing Authorisation to Pharmacia Limited, UK, on 05 January 2001.

Linezolid is a synthetic, antibacterial agent that belongs to a new class of antimicrobials, the oxazolidinones. It has *in vitro* activity against aerobic Gram positive bacteria and anaerobic microorganisms. Linezolid selectively inhibits bacterial protein synthesis via a unique mechanism of action. Specifically, it binds to a site on the bacterial ribosome (23S of the 50S subunit) and prevents the formation of a functional 70S initiation complex which is an essential component of the translation process.

The *in vitro* postantibiotic effect (PAE) of linezolid for *Staphylococcus aureus* was approximately 2 hours. When measured in animal models, the *in vivo* PAE was 3.6 and 3.9 hours for *Staphylococcus aureus* and *Streptococcus pneumoniae,* respectively. In animal studies, the key pharmacodynamic parameter for efficacy was the time for which the linezolid plasma level exceeded the minimum inhibitory concentration (MIC) for the infecting organism.

No new clinical or non-clinical studies were conducted, which is acceptable given that the application was based on being a generic medicinal product of an originator product that has been licensed for

over 10 years. As the product meets the criteria specified in the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**) a Biopharmaceutical Classification System (BCS)-based biowaiver was accepted and bioequivalence studies were not required.

The RMS has been assured that acceptable standards of Good Manufacturing Practice are in place for this product type at all sites responsible for the manufacture, assembly and batch release of these products.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the community, the RMS has accepted copies of current GMP Certificates or satisfactory inspection summary reports, 'close-out letters' or 'exchange of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

The RMS and CMS considered that the application could be approved at the end of procedure on 02 October 2018. After a subsequent national phase, a licence was granted in the UK on 22 October 2018.

II QUALITY ASPECTS

II.1 Introduction

Each tablet contains 600 mg of linezolid as the active ingredient. Other ingredients consist of the pharmaceutical excipients:

Tablet core

Pregelatinised starch (Lycatab C), mannitol (Pearlitol 160C), colloidal silicon dioxide, copovidone (Plasdone S 630), sodium stearyl fumarate.

Film coating (Opadry YS-1-18202-A White)

HPMC 2910/hypromellose, titanium dioxide and macrogol/PEG.

The finished product is packaged in:

- PVC/PVDC blister strips of 10 tablets. Each pack contains either 10, 20, 30, 50, 60 or 100 film-coated tablets.
- HDPE bottles with child resistant cap containing either 10, 14, 20, 24, 30, 50, 60 or 100 (for hospital use only) film-coated tablets.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

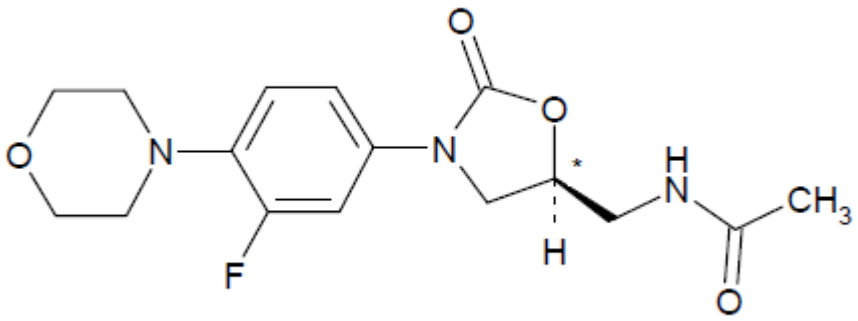
II.2 Drug Substance

INN: Linezolid

Chemical name: N-[[(5S)-3-[3-Fluoro-4-(4-morpholinyl) phenyl]-2-oxo-5-oxazolidinyl]methyl] acetamide

(S)-N-[[3-[3-Fluoro-4-(4morpholinyl)phenyl]-2-oxo-5-oxazolidinyl] methyl]-acetamide.

Structure:



Note:* indicates chiral centre

Molecular formula: $C_{16}H_{20}FN_3O_4$

Molecular weight: 337.35

Appearance: A white to off white crystalline powder.

Solubility: Freely soluble in chloroform, sparingly soluble in methanol.

An Active Substance Master File (ASMF) has been provided by the active substance manufacturer, covering the manufacture, control, packaging and stability of the active substance.

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specification limits. Satisfactory Certificates of Analysis have been provided for all working standards. Batch analysis data are provided that comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated to support a suitable retest period when stored in the proposed packaging.

II.3. Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious, film-coated tablets containing 600 mg linezolid per tablet, that are generic versions of the reference product, Zyvox 600 mg film-coated tablets (PL 00032/0261; Pharmacia Limited, UK). A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* dissolution and impurity profiles have been provided for the proposed and originator products.

All excipients comply with their respective United States Pharmacopeia and National Formulary (USP-NF) / European Pharmacopoeia (Ph.Eur) monographs with the exception of the film coat Opadry YS-1-18202-A White, which is controlled to a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients. Suitable batch analysis data have been provided for each excipient.

None of the excipients used contain material of animal or human origin.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacture of the product

Satisfactory batch formulae have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at pilot scale and has shown satisfactory results. The process validation protocol to be followed for full-scale production batches has been provided and is satisfactory.

Finished Product Specification

The finished product release and shelf life specifications proposed are acceptable. Test methods have been described that have been adequately validated. Batch data have been provided which comply with the release specification. Certificates of Analysis have been provided for all working standards used.

Stability of the Product

Finished product stability studies were performed in accordance with current guidelines on batches of the finished products in the packaging proposed for marketing. The data from these studies support a shelf-life of 3 years. This medicinal product does not require any special storage conditions.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

There are no objections to the approval of this application from a pharmaceutical viewpoint.

III NON-CLINICAL ASPECTS

III.1 Introduction

As the pharmacodynamic, pharmacokinetic and toxicological properties of linezolid are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant's non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.3 Pharmacokinetics

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.4 Toxicology

There are no toxicological concerns relating to the drug substance and product impurities or excipients.

III.5 Ecotoxicity/environmental risk assessment (ERA)

Since Linezolid tablets are intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

III.6 Discussion on the non-clinical aspects

There are no objections to the approval of this application from a non-clinical viewpoint.

IV CLINICAL ASPECTS

IV.1 Introduction

The clinical pharmacology of linezolid is well-known, no new pharmacodynamics or pharmacokinetic data are provided or are required for this application.

In line with the current guideline CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **, a BCS Class biowaiver is claimed for this application, on the following basis:

- Linezolid is a high soluble, high permeable Biopharmaceutics Classification System (BCS) Class I compound
- *In vitro* dissolution characteristics of the test and reference product has been demonstrated and found to be very rapid (> 85% within 15 min)
- It does not have a narrow therapeutic index

The data provided by the applicant are acceptable and sufficient in terms of the conditions laid down for a BCS-based biowaiver in the guideline on investigation of bioequivalence.

The presence of mannitol (which is not present in the reference product) has been justified by the applicant as having no adverse effect on the bioavailability of the finished product. Question 9 of the Q&A: positions on specific questions addressed to the Pharmacokinetics Working Party (PKWP) states that the best estimate of a single dose threshold for the sorbitol effect on drug bioavailability is probably around 1g. Therefore, it is reasonable to accept that the presence of mannitol in the finished product at a level lower than this threshold would not adversely affect bioavailability.

No new efficacy or safety studies have been performed and none are required for this type of application. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of linezolid.

Based on the data provided, Linezolid tablets can be considered bioequivalent to Zyvox 600 mg film-coated tablets (PL 00032/0261; Pharmacia Limited, UK)

IV.2 Pharmacokinetics

Linezolid is rapidly and extensively absorbed following oral dosing. Maximum plasma concentrations are reached within 2 hours of dosing. Absolute oral bioavailability of linezolid (oral and intravenous dosing in a crossover study) is extensive. Absorption is not significantly affected by food and absorption from the oral suspension is similar to that achieved with the film-coated tablets.
Steady-state conditions are achieved by the second day of dosing.

Volume of distribution at steady-state averages at about 40-50 litres in healthy adults and approximates to total body water. Plasma protein binding is about 31% and is not concentration dependent.

Linezolid is primarily metabolised by oxidation of the morpholine ring resulting mainly in the formation of two inactive open-ring carboxylic acid derivatives; the aminoethoxyacetic acid metabolite (PNU-142300) and the hydroxyethyl glycine metabolite (PNU-142586). The hydroxyethyl glycine metabolite (PNU-142586) is the predominant human metabolite and is believed to be formed by a non-enzymatic process. The aminoethoxyacetic acid metabolite (PNU-142300) is less abundant. Other minor, inactive metabolites have been characterised.

In patients with normal renal function or mild to moderate renal insufficiency, linezolid is primarily excreted under steady-state conditions in the urine as PNU-142586 (40%), parent drug (30%) and PNU-142300 (10%). Virtually no parent drug is found in the faeces whilst approximately 6% and 3% of each dose appears as PNU-142586 and PNU-142300, respectively. The elimination half-life of linezolid averages at about 5-7 hours. Non-renal clearance accounts for approximately 65% of the total clearance of linezolid. A small degree of non-linearity in clearance is observed with increasing doses of linezolid. This appears to be due to lower renal and non-renal clearance at higher linezolid concentrations. However, the difference in clearance is small and is not reflected in the apparent elimination half-life.

No new pharmacokinetic data were submitted and none were required for applications of this type. A BCS-based biowaiver is accepted.

IV.3 Pharmacodynamics

No new pharmacodynamic data were submitted and none were required for applications of this type.

IV.4 Clinical efficacy

No new efficacy data were submitted, and none were required for applications of this type.

IV.5 Clinical safety

No new safety data were submitted and none are required.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance System

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended.

There are no differences from the reference product in terms of proposed uses, maximum pack size / strength or pharmaceutical form / formulation that would have any implications for safety.

In line with the reference product, the applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns (labelling in the SmPC and the PIL). This is agreed.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

IV.7 Discussion on the clinical aspects

The grant of a marketing authorisation is recommended for this application from a clinical viewpoint.

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

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with linezolid is considered to have demonstrated the therapeutic value of the compound. The product is bioequivalent to the marketed reference product and their risks and benefits are considered similar. The benefit-risk is, therefore, considered to be positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The following text is the approved label text for this medicine, no label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained:

Label leaflet-Blister pack:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. NAME OF THE MEDICINAL PRODUCT

Linezolid 600 mg film-coated tablets
linezolid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 600 mg of Linezolid

3. LIST OF EXCIPIENTS

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4. PHARMACEUTICAL FORM AND CONTENTS

10 Tablets,
20 Tablets,
30 Tablets,
50 Tablets,
60 Tablets,
100 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

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8. EXPIRY DATE

EXP.:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Alkem Pharma GmbH
Gutenbergstrasse 13
Flensburg
Germany

12. MARKETING AUTHORIZATION NUMBER(S)

PL 35646/0067

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Linezolid #600 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

PARTICULARS TO APPEAR ON THE BLISTERS OR STRIPS

PVC/PVDC Blister (10 tablets)

1. NAME OF THE MEDICINAL PRODUCT

Linezolid 600 mg film-coated tablets
linezolid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Alkem Pharma GmbH

3. EXPIRY DATE

EXP.:

4. BATCH NUMBER

Batch:

5. OTHER

Label leaflet-bottle pack:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Linezolid 600 mg film-coated tablets
linezolid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 600 mg of Linezolid

3. LIST OF EXCIPIENTS

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4. PHARMACEUTICAL FORM AND CONTENTS

10 Tablets,
14 Tablets,
20 Tablets,
24 Tablets,
30 Tablets,
50 Tablets,
60 Tablets,
100 Tablets (for hospital use only)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP.:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Alkem Pharma GmbH
Gutenbergstrasse 13
Flensburg
Germany

12. MARKETING AUTHORIZATION NUMBER(S)

PL 35646/0067

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Linezolid #600 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

Annex 1

Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Scope	Procedure number	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached Y/N (version)