IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Micafungin 100 mg powder for concentrate for solution for infusion
Micafungin
PA0281/221/002

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Micafungin 50 mg and 100 mg powder for concentrate for solution for infusion from Pinewood Laboratories Ltd. on 19th March 2021 for:

Adults, adolescents ≥ 16 years of age and elderly:
- Treatment of invasive candidiasis.
- Treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate.
- Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells / µl) for 10 or more days.

Children (including neonates) and adolescents < 16 years of age:
- Treatment of invasive candidiasis.
- Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells / µl) for 10 or more days.

The Summary of Product Characteristics for (SmPC) for this medicinal product is available on the HPRA's website at wwwhpra.ie

Name of the product	Micafungin 50 mg & 100 mg powder for concentrate for solution for infusion
Name(s) of the active substance(s) (INN)	Micafungin
Pharmacotherapeutic classification (ATC code)	Micafungin J02AX05
Pharmaceutical form and strength(s)	Powder for concentrate for solution for infusion
Marketing Authorisation Number(s) in Ireland (PA)	PA0281/221/001-002
Marketing Authorisation Holder	Pinewood Laboratories Ltd, Ballymacarbry, Clonmel, Co. Tipperary, Ireland
MRP/DCP No.	IE/H/1148/001-002/DC
Reference Member State	IE (transferred from DE to IE 07/10/2020)
Concerned Member State	DE, FR, UK

II. QUALITY ASPECTS

II.1. Introduction

This application is for Micafungin 50 mg and 100 mg powder for concentrate for solution for infusion.

II.2 Drug substance

The active substance is Micafungin, an established active substance not described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur..

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for parenteral preparations, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.7 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging complies with Ph. Eur. requirements.

P.8 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Discussion on Chemical, Pharmaceutical Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Micafungin 50 mg and 100 mg powder for concentrate for solution for infusion.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is a generic formulation of Mycamine Powder for Solution for Infusion, 50 mg/vial, 100 mg/vial on the European market. No new preclinical data have been submitted.

III.2 Ecotoxicity/environmental risk assessment

Since Micafungin 50 mg and 100 mg powder for concentrate for solution for infusion is a generic product, it will not lead to an increased exposure to the environment. An environmental risk assessment is, therefore not deemed necessary

III.3 Discussion on the non-clinical aspects

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

Non-clinical findings are adequately represented in the appropriate sections of the SmPC.

IV. CLINICAL ASPECTS

Micafungin is a well known active substance with established efficacy and tolerability.

For this generic application, the applicant has not submitted a bioequivalence study.

A bioequivalence study is not necessary according to the Guideline on the investigation of Bioequivalence (CHMP/QWP/EWP/1401/98 Rev. 1) since the product is an aqueous parenteral solution.

The content of the SmPC approved during the Decentralised procedure is in accordance with that accepted for the reference product Mycamine Powder for Solution for Infusion, 50 mg/vial, 100 mg/vial by Astellas Pharma, registered since 29.04.2008.

V. OVERALL CONCLUSIONS

The benefit-risk is considered positive.

VI. REVISION DATE

27.07.2025