IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Fosfomycin Ascend 3 g granules for oral solution
Fosfomycin trometamol
PA23429/008/001

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.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Fosfomycin Ascend 3g Granules for oral solution, from Ascend GmbH on 18/03/2025 for the treatment of acute, uncomplicated cystitis in women and female adolescents on 4th April 2025.

The application is submitted in accordance with Article 10(1) of Directive 2001/83/EC, a generic application, with Ireland as the Reference Member State and Germany as the only Concerned Member State

No EMA Scientific Advice was requested by the applicant for the proposed medicinal product, nor was it requested from the RMS or CMS.

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

Name of the product:	Fosfomycin Ascend 3g Granules for oral solution
Name(s) of the active substance(s) (INN)	fosfomycin trometamol
Pharmacotherapeutic classification (ATC code)	J01XX01
Pharmaceutical form and strength(s)	3g Granules for oral solution
Marketing Authorisation Number(s) in Ireland (PA)	PA23429/008/001
Marketing Authorisation Holder	Ascend GmbH
MRP/DCP No.	IE/H/1311/001/DC
Reference Member State	IE
Concerned Member State	DE

II. QUALITY ASPECTS

II.1. Introduction

This application is for Fosfomycin 3 g granules for oral solution.

II.2 Drug substance

The active substance is fosfomycin trometamol, an established active substance 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

Each single-dose sachet contains 5.631 g of fosfomycin trometamol equivalent to 3 g fosfomycin.

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 guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for the dosage form, 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(s) have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 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 EU legislation for use with foodstuffs requirements.

P.7 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 and Biological 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 Fosfomycin Ascend 3g Granules for oral solution.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is a generic formulation of Monuril 3g on the European market. As the pharmacodynamic, pharmacokinetic and toxicological properties of Fosfomycin are well known, the applicant has not provided additional nonclinical studies, and further studies are not required. The overview provided based on literature review is thus appropriate.

III.2 Pharmacology

N/A

III.3 Pharmacokinetics

N/A

III.4 Toxicology

N/A

III.5 Ecotoxicity/environmental risk assessment

As Fosfomycin is 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

Pharmacodynamic, pharmacokinetic and toxicological properties of Fosfomycin are well known since the reference product Monuril has been marketed since 1995 and resulting clinical experience is extensive. As Fosfomycin is a widely used, well-known active substance, the applicant has not provided additional nonclinical studies, and further studies are not required. The nonclinical overview on the nonclinical pharmacology, pharmacokinetics and toxicology provided is adequate.

IV. CLINICAL ASPECTS

IV.1 Introduction

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

The content of the SmPC approved during the decentralised procedure is generally in accordance with that accepted for the reference product Monuril 3 g granules for oral solution marketed by Zambon GmbH.

As agreed during the application procedure, the generic product has fewer indications than the cited reference product. It is indicated for the treatment of acute, uncomplicated cystitis in women and female adolescents only.

Justification for the absence of bioequivalence studies has been provided.

IV.2 Pharmacokinetics

The applicant requested a waiver to bioequivalence testing between the test and reference products in accordance with EMA guidance. The biowaiver was granted. No new pharmacokinetic studies were completed which is acceptable for this type of application.

IV.3 Pharmacodynamics

No new studies were performed or required for this abridged/generic application.

IV.4 Clinical Efficacy

No new clinical studies were completed which is acceptable for an abridged/generic application.

IV.5 Clinical Safety

No new clinical studies were completed which is acceptable for an abridged/generic application.

IV.6 Discussion on the clinical aspects

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

The content of the SmPC approved during the decentralised procedure is generally in accordance with that accepted for the reference product Monuril 3 g granules for oral solution marketed by Zambon GmbH. As agreed during the application procedure, the generic product has fewer indications than the cited reference product. It is indicated for the treatment of acute, uncomplicated cystitis in women and female adolescents only.

Abridged applications avoid the need for repetitive tests on humans and justification for the absence of bioequivalence studies has been provided.

V. OVERALL CONCLUSIONS

Fosfomycin Ascend 3g Granules for oral solution is a generic form of Monuril 3 g granules for oral solution. Monuril 3 g granules for oral solution is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

Justification for the absence of bioequivalence studies has been provided.

The SmPC, Patient Leaflet and labelling are satisfactory, and broadly in line with current guidelines and consistent with that of the reference product.

As agreed during the application procedure, the generic product has fewer indications than the cited reference product. It is indicated for the treatment of acute, uncomplicated cystitis in women and female adolescents only.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The HPRA, on the basis of the data submitted considered that Fosfomycin Ascend 3g Granules for oral solution demonstrated bioequivalence with the reference product as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI. REVISION DATE

14.03.2030