IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

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 Desloratadine 5mg Film-coated Tablets from Accord healthcare Ltd on 3rd March 2019 for adults and adolescents aged 12 years and older for the relief of symptoms associated with:
- allergic rhinitis
- urticaria

This is a decentralised application for Desloratadine 5mg film-coated tablets. The HPRA was the RMS and the UK (Northen Ireland) was the only CMS. The active substance is Desloratadine. The submitted dossier has already undergone assessment in the centralised procedure EMEA/H/C/002435 which concluded positively on 13/01/2012.

The legal basis of this application is Article 10(1) of Directive 2001/83/EC. The products concerned are considered essentially similar to Aerius 5 mg film-coated tablets as marketed in the European Union. The reference medicinal product Aerius was first authorised for use in the European Union on 15th January 2001 (EMEA/H/C/000313).

Desloratadine 5mg Film-coated Tablets is subject to prescription.

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

Name of the product	Desloratadine 5mg Film-coated Tablets
Name(s) of the active substance(s) (INN)	Desloratidine
Pharmacotherapeutic classification (ATC code)	M05BA04 Alendronic acid
Pharmaceutical form and strength(s)	5mg Film-coated Tablets
Marketing Authorisation Number(s) in Ireland (PA)	PA 2315/016/001
Marketing Authorisation Holder	Accord Healthcare Ireland Ltd
MRP/DCP No.	IE/H/546/001/DC
Reference Member State	IE
Concerned Member State	XI (Northern Ireland)

II. QUALITY ASPECTS

II.1. Introduction

This application is for Desloratadine 5mg Film-coated Tablets.

II.2 Drug substance

The active substance is Desloratadine, 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
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 and ICH 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 tablets, 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 Ph. Eur. and 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 Desloratadine 5mg Film-coated Tablets.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is a generic formulation of Aerius 5mg tablets on the European market. No new preclinical data have been submitted. As such, no pre-clinical assessment has been made on the application. This is acceptable for this type of application.

The pharmacodynamic, pharmacokinetic and toxicological properties of desloratadine are well known. As desloratadine is a widely used, well-known active substances, and this is a generic application, 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 Ecotoxicity/environmental risk assessment

Since Desloratadine 5mg film-coated tablets 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.3 Discussion on the non-clinical aspects

The pharmacodynamic, pharmacokinetic and toxicological properties of desloratadine are well known. As desloratadine is a widely used, well-known active substances, and this is a generic application, the applicant has not provided additional nonclinical studies and further studies are not required. The non-clinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology provided is adequate. Non-clinical findings are adequately represented in the appropriate sections of the SmPC.

IV. CLINICAL ASPECTS

IV.1 Introduction

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

The content of the SmPC approved during the decentralised procedure is in accordance with that accepted for the reference product Aerius film coated tablets marketed by SP Europe.

For this generic application, the applicant has submitted one bioequivalence study in which the pharmacokinetic profile of the test product Desloratadine 5mg film-coated tablets is compared with the pharmacokinetic profile of the reference product Aerius 5 mg.

A single-dose, randomised, two-period, two-treatment, two-sequence, crossover bioequivalence study was carried out. Desloratadine film-coated tablets Actavis Group PTC ehf, Iceland, was compared to the reference product Aerius ® 5 mg tablets of SP Europe.

Based on the pharmacokinetic parameters of active substance and metabolite, the reference tablet Aerius ® 5 mg tablets marketed by SP Europe, and test tablet Desloratadine film-coated tablets are bioequivalent with extent to the rate and extent of absorption and fulfil the bioequivalence requirements outlined in the relevant CHMP Note for Guidance.

The SmPC is in line with the reference product Aerius.

IV.2 Pharmacokinetics

The applicant has provided a clinical overview outlining the pharmacokinetics of Desloratadine based on literature; this is considered acceptable.

IV.3 Pharmacodynamics

The applicant has provided a clinical overview outlining the pharmacodynamics of Desloratadine based on literature; this is considered acceptable.

No new pharmacodynamic studies were presented and no such studies are required for this application

IV.4 Clinical Efficacy

The efficacy of Desloratadine has been demonstrated in several well-controlled studies. A summary of these studies can be found in the EPAR of the reference product Aerius which was first authorised for use in the European Union on 15th January 2001 (EMEA/H/C/000313).

IV.5 Clinical Safety

The safety of Desloratadine has been demonstrated in several well-controlled studies. A summary of these studies can be found in the EPAR of the reference product Aerius (EMEA/H/C/000313).

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. Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed. Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

IV.6 Discussion on the clinical aspects

The legal basis of this application is Article 10(1) of Directive 2001/83/EC. The products concerned are considered essentially similar to Aerius 5 mg film-coated tablets as marketed in the European Union. The reference medicinal product Aerius was first authorised for use in the European Union on 15th January 2001 (EMEA/H/C/000313).

From a clinical perspective, this application does not contain new data on the pharmacokinetics and pharmacodynamics nor new data on the efficacy and safety of the active substance; the applicant's clinical overview on these clinical aspects based on information from published literature was considered sufficient.

The bioequivalence study submitted during the centralised procedure (EMEA/H/C/002435)
was considered adequate to evaluate the bioequivalence of Desloratadine 5mg Film-coated Tablets with Aerius 5 mg film-coated tablets and are in line with the respective European requirements.
A benefit/risk ratio comparable to the reference product can therefore be concluded.

V. OVERALL CONCLUSIONS

Desloratadine 5mg Film-coated Tablets indicated is a generic form of Aerius 5mg.

Aerius 5mg is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

Bioequivalence has been shown to be in compliance with the CHMP guidance documents. The SmPC is consistent with that of the reference product.

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 Desloratadine 5mg Film-coated Tablets demonstrated bioequivalence with the reference product as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI. REVISION DATE

03.03.2024