

**IPAR**



**Public Assessment Report for a  
Medicinal Product for Human Use**

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Scientific Discussion

Deslor 0.5 mg/ml oral solution  
Desloratadine  
PA0711/202/002

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.

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## I. INTRODUCTION

This product was initially authorised under procedure number DK/H/2038/002 with Denmark as RMS. The responsibility of RMS was transferred to Ireland on 23 March 2021 under procedure number IE/H/1186/002

Please note the following detail for the product in IE:

Marketing Authorisation Number: PA0711/202/002

Marketing Authorisation Holder: Rowex Ltd

The current Summary of Product Characteristics (SmPC) for this medicinal product is available on the HPRA website at [www.hpra.ie](http://www.hpra.ie).

The Danish public assessment report published at the time of the initial marketing authorisation is provided herein.

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Deslor 0.5 mg/ml oral solution, from Rowex Ltd.

The product is indicated for the relief of symptoms associated with allergic rhinitis and urticaria. A comprehensive description of the indications and posology is given in the SmPC.

Desloratadine is a non-sedating, long-acting antihistamine with selective peripheral H<sub>1</sub>-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H<sub>1</sub>- receptors because the substance is excluded from entry to the central nervous system.

This decentralised procedure concerns a generic application claiming essential similarity with the reference product Aerius 0.5 mg/ml oral solution, which has been registered in Europe by SP Europe since 2007.

## II. QUALITY ASPECTS

### II.1 Introduction

Each ml of oral solution contains 0.5 mg desloratadine. The solution is clear, colourless and free from foreign matter.

The oral solution is supplied in Type III amber glass bottles closed with a polypropylene child resistant (C/R) screw closure having a multi-ply polyethylene-faced liner.

The bottles are subsequently packed into cardboard boxes. All packages are supplied with a measuring spoon CE 0373 marked for doses of 2.5 ml and 5 ml or an oral measuring syringe CE 0373 of a final volume of 5 ml marked on every 0.5 ml.

The oral solution is supplied in 100 ml and is packaged in 100 ml bottles. However, not all pack sizes may be marketed

The oral solution contains: Sorbitol, liquid non-crystallizing (E0420); Propylene glycol; Citric acid monohydrate; Sodium citrate; Hypromellose 2910; Sucralose; Disodium edetate; Tutti frutti flavouring and Purified water.

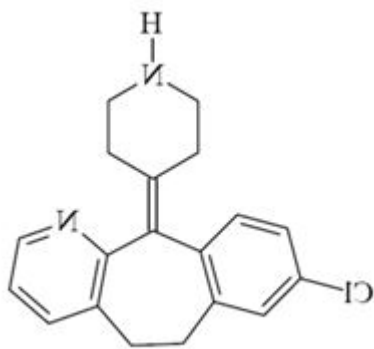
The RMS has been assured that acceptable standards of GMP (see Directive 2003/94/EC) are in place for this product type at all sites responsible for the manufacturing of the active substance as well as for the manufacturing and assembly of this product prior to granting its national authorisation.

### II.2 Drug Substance

The active substance, desloratadine, is not described in the European Pharmacopoeia. It is a white to off-white powder with pinkish background powder. It is soluble in chloroform and insoluble in water. It is not optically active.

Chemical name(s): 8-Chloro-6,11-dihydro-11-(4-piperidinylidene)-5H-benzo [5,6] cyclohepta [1,2-b] Pyridine

Molecular structure:



Molecular formula: C<sub>19</sub>H<sub>19</sub>ClN<sub>2</sub>

Molecular mass: 310.83

The documentation on the active substance is presented as a Drug Master File.

The description of the manufacturing process provided in the DMF is considered adequate. An adequate discussion of potential impurities is included and the control tests and specifications for the drug substance are almost adequately drawn up. A sufficient justification for not including a routine test for methanol in the specification is provided.

Stability studies according to ICH guidelines have been performed and the proposed retest period is accepted.

### 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. Acceptable validations of the analytical methods have been presented. Batch analysis has been performed on 3 batches. The batch analysis results show that the finished product meet the proposed specifications.

The conditions used in the formal stability studies are according to the ICH stability guideline. The control tests and specifications for drug product are adequately drawn up.

Stability data is provided to support the proposed shelf-life of 30 months with no special precautions for storage.

## III. NON-CLINICAL ASPECTS

### III.1 Introduction

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

The non-clinical overview report refers several publications up to year 2009. The non-clinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology is adequate.

### III.2 Ecotoxicity/environmental risk assessment (ERA)

Since Deslor 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.

## IV. CLINICAL ASPECTS

### IV.1 Introduction

Desloratadine is a well-known active substance with established efficacy and tolerability. As desloratadine is a widely used, well-known active substance, the MAH has not provided additional studies and further studies are not required. Overview based on literature review is, thus, appropriate.

A waiver of in vivo bioequivalence studies is requested. The finished product is an oral solution with a composition which is qualitatively very similar to the reference product and the content of excipients with potential impact on the bioavailability is quantitatively very similar to the reference product. Therefore, it is justified according to *The Guideline on the Investigation of Bioequivalence* to waive bioequivalence studies.

The clinical report refers several publications up to year 2010. The clinical overview on the clinical pharmacology, efficacy and safety is adequate.

#### IV.2 Risk Management Plan

As the dossier in question refers to a generic product with an active substance which has been marketed throughout the EU for more than 10 years and of which the safety profile has not been disputed so far, the MAH considers routine pharmacovigilance sufficient without any need for further risk minimisation measures. The RMS endorses this position.

### V. OVERALL CONCLUSIONS

Deslor 0.5 mg/ml oral solution has a proven chemical-pharmaceutical quality and is a generic form of Aeries. Aeries is a well-known medicinal product with an established favourable efficacy and safety profile.

A waiver of in vivo bioequivalence studies was requested and approved.

Agreement between Member States was reached during a written procedure. There was no discussion in the CMD(h). The Concerned Member States, on the basis of the data submitted, considered that essential similarity had been demonstrated for Deslor with the reference product, and therefore granted a marketing authorisation. The decentralised procedure was finalised on 20 March 2012. Deslor was authorised in Denmark on 12 September 2012.

According to the List of Union reference dates and frequency of submission of periodic safety update reports (PSURs), PSURs should be submitted every 5 years. The next PSUR should be submitted with a DLP of 15 July 2016.

The date for the first renewal will be: 20 March 2017.

There were no post-approval commitments made during the procedure.

### VI. REVISION DATE

24 April 2024

### VII. UPDATES

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
RMS transfer	From DK/H/2038/002 to IE/H/1186/002	N/A	23 March 2021	N/A