LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Public Assessment Report
# Scientific discussion

# Desloratadin NET
# (desloratadine)

**This module reflects the scientific discussion for the approval of Desloratadin NET. The procedure was finalised on 2022-10-05. For information on changes after this date please refer to the module 'Update'.**

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# I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Desloratadin NET, 0,5 mg/ml, Oral solution.

The active substance is desloratadine. A comprehensive description of the indication and posology is given in the SmPC.

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

The application for Desloratadin NET, 0,5 mg/ml, Oral solution is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Evolan Pharma AB applies for a marketing authorisation in Sweden through a National Procedure.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Aerius, 0,5 mg/ml, Oral lösning authorised in Union since 2001, with NV Organon as marketing authorisation holder.

**Potential similarity with orphan medicinal products**

According to the application form and a check of the Community Register of orphan medicinal products there is no medicinal product designated as an orphan medicinal product for a condition relating to the indication proposed in this application.

# II. QUALITY ASPECTS

## II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

## II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

# III. NON-CLINICAL ASPECTS

Pharmacodynamic, pharmacokinetic and toxicological properties of desloratadine are well known. As desloratadine is a widely used, well-known active substance, no further studies are required and the applicant provides none. Overview based on literature review is, thus, appropriate.

**Environmental Risk Assessment (ERA)**
Since Desloratadin NET is a generic product, it will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

There are no objections to approval of Desloratadin NET from a non-clinical point of view.

# IV. CLINICAL ASPECTS

**Pharmacokinetics**
Desloratadine is well absorbed and the bioavailability is dose proportional over the range of 5 mg to 20 mg. There are no restrictions with respect to food in the SmPC of the originator. The terminal half-life is approximately 27 hours.

To support the application for a generic oral solution, the applicant has submitted a biowaiver justification.

Discussion and overall conclusion
According to the Guideline on the investigation of Bioequivalence (CHMP/QWP/EWP/1401/98 Rev. 1), bioequivalence studies may be waived if the test product is an aqueous oral solution at time of administration and contains the same concentration of the active substance as the approved reference oral solution.

The absence of bioequivalence studies is acceptable since the applied product is an aqueous oral solution with the same concentration of the active substance as the approved reference oral solution. Furthermore, the applied product contains similar amount of excipient that may affect bioavailability.

The classification of desloratadine as a BCS 1 substance is supported by literature reference(s) submitted by the applicant.

For quality aspects of biowaiver, see the quality assessment report.

**Pharmacodynamics/Clinical efficacy/Clinical safety**

No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted, which is acceptable.

# V. USER CONSULTATION
A user consultation with target patient groups on the package leaflet has been performed on the basis of a bridging report making reference to Desloratadin Cipla 5 mg tablets SE/H/1136/01/DC. The bridging report submitted by the applicant has been found acceptable.

# VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Desloratadin NET, is found adequate. There are no objections to approval of Desloratadin NET, from a non-clinical and clinical point of view. The absence of bioequivalence studies is acceptable. The product information is acceptable. The application is therefore recommended for approval.

**List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment**

N/A

**List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC**

N/A

# VII. APPROVAL

Desloratadin NET, 0,5 mg/ml, Oral solution was approved in the national procedure on 2022-10-05.

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# Public Assessment Report – Update

| Procedure number* | Scope | Product Information affected (Yes/No) | Date of end of procedure | Approval/ non approval | Summary/ Justification for refuse |
|---|---|---|---|---|---|
| | | | | | |

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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