LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Mometasone furoate/Olopatadine Glenmark
(mometasone furoate, olopatadine hydrochloride)

SE/H/2538/01/DC

This module reflects the scientific discussion for the approval of Mometasone furoate/Olopatadine Glenmark. The procedure was finalised on 2024-10-29. 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 Mometasone furoate/Olopatadine Glenmark, 25 mikrogram/dos + 600 mikrogram/dos, Nasal spray, suspension.

The active substance is mometasone furoate, olopatadine hydrochloride. 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 Mometasone furoate/Olopatadine Glenmark, 25 microgram/dose + 600 microgram/dose, Nasal spray, suspension, is an Informed consent Art. 10c application submitted according to Directive 2001/83/EC. The applicant applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and IT as the sole concerned member state (CMS).

Reference is made to a marketing authorisation granted to Glenmark Pharmaceuticals s.r.o., for the product Ryaltris, 25 microgram/dose + 600 microgram/dose, Nasal spray, suspension, approved in Sweden in 2021 via a Decentralised procedure on the basis of Article 10b of Directive 2001/83/EC as amended. The CMS for this application is included as CMS also for Ryaltris (SE/H/2040). Consequently, the Day 70 PrAR only contains an overview. Mometasone furoate/Olopatadine Glenmark has the same composition and the same pharmaceutical form as Ryaltris.

Potential similarity with orphan medicinal products
N/A

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

The application procedure for Mometasone furoate/Olopatadine Glenmark SE/H/2538/01/DC is an informed consent application, the non-clinical data in support of Mometasone furoate/Olopatadine Glenmark SE/H/2538/01/DC application are identical to the non-clinical data of Ryaltris SE/H/2040/01/DC dossier which have been assessed and approved in all countries being subject of this application procedure.

Environmental Risk Assessment (ERA)
An ERA for each of the active substances identical to those submitted for Ryaltris have been provided. However, the assessment of the ERAs for Ryaltris generated a post approval commitment:

Conclusions on ERAs for Ryaltris: The active substances (MOM, OLP) are not PBT candidates but a final environmental risk assessment cannot be finalized until the various concerns have been resolved. The applicant is committed to providing missing studies and an updated ERA before Q4 2023.

Of note, the date was later changed to Q2 2024.

This post approval commitment is being assessed in a variation application for Ryaltris. Based on the updated ERA, changes in SmPC 5.3 and SmPC 6.6 have been proposed and are deemed acceptable.

There are no objections to approval of Mometasone furoate/Olopatadine Glenmark from a non-clinical point of view.

IV. CLINICAL ASPECTS

The application procedure for Mometasone furoate/Olopatadine Glenmark SE/H/2538/01/DC is an informed consent application, the clinical data in support of Mometasone furoate/Olopatadine Glenmark SE/H/2538/01/DC application are identical to the clinical data of Ryaltris. SE/H/2040/01/DC dossier which have been assessed and approved in all countries being subject of this application procedure.

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 relating to Mometasone furoate/Olopatadine Glenmark.

The submitted RMP is identical to the RMP of Ryaltris SE/H/2040/01/DC dossier which have been assessed and approved in all countries being subject of this application procedure.

Part II Safety specification

Important identified risk(s)	• None
Important potential risk(s)	• None
Missing information	• Use in pregnancy and lactation

Part III Pharmacovigilance Plan

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

Part V Risk minimisation measures
Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Part VI Summary of the RMP
The Summary of the RMP is endorsed.

Conclusion RMP assessment
The submitted Risk Management Plan, version 0.2 signed 4 November 2020 is considered acceptable.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. USER CONSULTATION

The applicant declares that the leaflet has the same **wording, layout and design** as the leaflet of the informed consent reference procedure SE/H/2040/01/DC. Therefore, no user testing or bridging report was provided.

It is agreed with the applicant that no user testing is necessary in this case, since the leaflet of procedure SE/H/2040/01/DC was successfully evaluated via a full user consultation study, in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The application procedure for Mometasone furoate/Olopatadine Glenmark SE/H/2538/01/DC is an informed consent application. The quality, non-clinical, and clinical data in support of Mometasone furoate/Olopatadine Glenmark SE/H/2538/01/DC application are identical to the quality, non-clinical, and clinical data of Ryaltris SE/H/2040/01/DC dossier which have already been assessed and approved in all countries being subject of this application procedure. The benefit risk of this application is considered positive, and the application is therefore approvable.

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

The decentralised procedure for Mometasone furoate/Olopatadine Glenmark, 25 mikrogram/dos + 600 mikrogram/dos, Nasal spray, suspension was positively finalised on 2024-10-29.

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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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