LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Nasoferm Mentol
(xylometazoline hydrochloride)

Asp no: 2020-0086

This module reflects the scientific discussion for the approval of Nasoferm Mentol. The procedure was finalised on 2021-10-29. 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 Nasoferm Mentol, 1 mg/ml, Nasal spray, solution.

The active substance is xylometazoline, xylometazoline 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 Nasoferm Mentol, 1 mg/ml, nasal spray, solution, is a hybrid application submitted according to Article 10(3) of Directive 2001/83/EC. The applicant, Nordic Drugs 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 Otrivin Xylometazoline HCl Menthol, 1 mg/ml, Nasal spray, solution authorised in NL since 1996, with GlaxoSmithKline 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 xylometazoline are well known. As xylometazoline 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 Nasoferm Mentol is intended for substitution with marketed products containing the same active substance, 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 Nasoferm Mentol from a non-clinical point of view.

IV. CLINICAL ASPECTS

Pharmacokinetics
No studies have been conducted. Xylometazoline is a locally acting locally applied drug with very low systemic availability. Bioequivalence studies are therefore not relevant to assess therapeutic equivalence with the originator. The assessment of equivalence will therefore rely on quality data.

Pharmacodynamics
No new data have been submitted. No data are required for an abridged application provided therapeutic equivalence has been satisfactorily demonstrated.

Clinical efficacy
No new data have been submitted. No data are required for an abridged application provided therapeutic equivalence has been satisfactorily demonstrated.

Clinical safety
No new data have been submitted. No data are required for an abridged application provided therapeutic equivalence has been satisfactorily demonstrated.

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 Nasoferm Mentol.

Safety specification
There are no important risks or missing information listed which is appropriate for this product.

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

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

Summary of the RMP
The submitted Risk Management Plan, version 0.2 signed March 15, 2021 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 MPA;
- 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

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Otrinex 1mg/ml. The user test of the Otrinex 1 mg/ml leaflet was assessed and accepted in national procedure 5.4.1-2015-14246. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the product, Nasoferm Mentol, is found adequate. There are no objections to approval of Nasoferm Mentol, from a non-clinical and clinical point of view. The product information is acceptable. The benefit/risk ratio is considered positive and Nasoferm Mentol, 1 mg/ml, nasal spray, solution, is 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

Nasoferm Mentol, 1 mg/ml, Nasal spray, solution was approved in the national procedure on 2021-10-29.

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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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