LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Natriumfluorid Mimer
(sodium fluoride)

Asp no : 2016-0135

This module reflects the scientific discussion for the approval of Natriumfluorid Mimer. The procedure was finalised on 2016-03-17. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Mimer Medical AB has applied for a marketing authorisation for Natriumfluorid Mimer, mouth wash, 0.2 %. The active substance is sodium fluoride, which works through enhancing the remineralization of early stages of caries and by inhibiting demineralization, which would lead to dental caries.

For approved indications, see the Summary of Product Characteristics.

The marketing authorisation has been granted pursuant to Article 10(3) of Directive 2001/83/EC.

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

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

III.1 Discussion on non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

III.2 Ecotoxicity/environmental risk assessment

Since Natriumfluorid Mimer, mouth wash, 0.2 % 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 Pharmacokinetics

The product applied for, Natriumfluorid Mimer, mouth wash, 0.2 %, is to be administered locally in the mouth and should be spit out after use. However, literature data has shown a statistically significant increase of fluoride ion in urine, which can be attributed to the use of a fluoride mouth wash in children, This shows that even though this product is locally applied in the mouth, some floride is systemically available. If this is due to mouth uptake of floride or swallowed solution is unknown.

IV.2 Pharmacodynamics / Clinical efficacy / Clinical safety

No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted. Provided that bioequivalence with the originator product is demonstrated, additional data is not necessary.

IV.3 Risk Management Plans

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 Natriumfluorid Mimer.

Safety specification

Summary table of safety concerns as approved in RMP

Important identified risks	*Hypersensitivity* *Acute toxic reaction* *Exanthema*
Important potential risks	*Enamel fluorosis*
Missing information	*None*

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 RMP is approved.

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The benefit/risk ratio is considered positive and Natriumfluorid Mimer, 0.2 %, mouth wash is recommended for approval.

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

N/A

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

N/A

VII. APPROVAL

Natriumfluorid Mimer, 0.2 %, mouth wash was approved in the national procedure on 2016-03-17.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected	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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