LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Minoxidil Orifarm
(minoxidil)

Asp no: 2025-0354

This module reflects the scientific discussion for the approval of Minoxidil Orifarm. The procedure was finalised at 2026-02-27. For information on changes after this date please refer to the module 'Steps taken after the finalisation of the initial procedure - Summary'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have agreed to grant a marketing authorisation for Minoxidil Orifarm, 50 mg/g, Cutaneous foam.

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

II. EXECUTIVE SUMMARY

II.1 About the product

The medicinal product proposed for marketing, Minoxidil Orifarm, is manufactured in the form of a cutaneous foam and 1g contains 50 mg of minoxidil as the active ingredient. Minoxidil belongs to the pharmaceutical class: *Other dermatological preparations, Other dermatologicals* with Anatomical Therapeutic Chemical (ATC) Classification System code D11AX01.

Minoxidil Orifarm is indicated for the treatment of androgenetic alopecia in men. Treatment with Minoxidil, 50 mg/g, cutaneous foam is suggested to stimulate hair growth and counteract the progression of androgenetic alopecia.

The mechanism by which topical minoxidil acts is not yet clear.
Minoxidil may stimulate hair growth and stop hair loss in the following ways:
• Increase in the hair diameter.
• Stimulation of hair growth in the anagen phase.
• Prolongation of the anagen phase.
• Stimulation of return to the anagen phase from the telogen phase.

Minoxidil Orifarm should be administered according to the following posology:
Adult men above 18 years of age: 1 g Minoxidil Orifarm to the scalp twice daily (morning and evening), maximum daily dose is 2 g Minoxidil Orifarm.

The proposed risk management strategy implies routine risk minimisation..

II.2 General comments on the submitted dossier

The application for Minoxidil Orifarm, 50 mg/g, Cutaneous foam, is a Hybrid Art. 10(3) application submitted according to Directive 2001/83/EC. The applicant 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 Rogaine, 50 mg/g, Cutaneous foam authorised in Sweden since 2012 with McNeil Sweden AB as marketing authorisation holder.

II.3 General comments on compliance with GMP, GLP, GCP and agreed ethical principles

The MPA has been assured that acceptable standards of GMP are in place for these product types at all sites responsible for the manufacture and assembly of this product.

For manufacturing sites within the European Community, the MPA has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the European Community, the MPA has accepted copies of current GMP Certificates of satisfactory inspection summary reports, 'close-out letters' or 'exchange of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

GMP active substance
Regarding the statement on GMP for the active substance a statement/declaration is provided from the manufacturer(s) responsible for manufacture of the finished product and batch release situated in the EU.

III. SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 Quality aspects

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.

Drug 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.2 Non-clinical aspects

Pharmacology/Pharmacokinetics/Toxicology

Pharmacodynamic, pharmacokinetic and toxicological properties of minoxidil are well known. As minoxidil is a widely used, well-known active substance, no further studies are required, nor does the applicant provide any. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)

An ERA document was submitted for Minoxidil Orifarm which is based on the conclusions made in another approved ERA in EU. Based on the provided PARs, no environmental risks were identified for minoxidil based on Phase 1 and Phase 2A data. However, short of additional data based on the new GL, it is not possible to know if all aspects have been evaluated.
Therefore, the data presented are not considered sufficient to conclude on whether the ERA fulfils the requirements of the new ERA guideline. For this national application, the data can be considered sufficient, but this is likely to change with the new legislation and may not be sufficient for further procedures unless the data are completed.

III.3 Clinical aspects

Pharmacokinetics
Minoxidil cutaneous foam 50 mg/g is a product intended for local use (on the scalp) and it exerts the effect at the site of application. The systemic absorption of topically applied minoxidil from normal intact skin is low.
No bioequivalence study or other permeation kinetic studies have been performed for this product compared to the reference product Rogaine cutaneous foam 50 mg/g.
The omission of data from permeation kinetic studies and clinical studies has been discussed and justified in accordance with the Guideline on quality and equivalence of locally applied, locally acting cutaneous products EMA/CHMP/QWP/708282/2018 Corr.1*.
Therapeutic equivalence can be concluded based on quality data.

Pharmacodynamics
Topically administered minoxidil is supposed to stimulate hair growth in patients with early and moderate hair loss, but its mechanism of action is still not well-established. The action of the drug is dependent neither on the hormonal factor nor on the inhibitory effect on 5-alpha-reductase.

Clinical efficacy
Topical treatment with different pharmaceutical formulations and different strengths of minoxidil has been in clinical use for more than 30 years in both men and women with androgenetic alopecia.

The clinical effects of topical minoxidil are closely related to continuous use of the drug product and disappear after discontinuation of drug treatment.

Clinical safety
The safety profile of topical minoxidil is well known. The occurrence of adverse reactions associated with topical minoxidil is usually common, uncommon or not known, however their character is mild.

Pharmacovigilance system

Proposed MAH: Orifarm Healthcare A/S
The Applicant has submitted a signed Summary of the Applicant's/Proposed Future MAH's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies

with the new legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the MPA considers the Summary acceptable.

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 Minoxidil Orifarm.

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 1.0 signed 10.12.2025 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.

Periodic Safety Update Report (PSUR)
Active substance is currently listed in the published EURD list

With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.

- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.

- In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.>

Renewal date
The renewal date will be 5 years after approval date.

IV. BENEFIT RISK ASSESSMENT

The quality of the generic product, Minoxidil Orifarm, is found adequate. There are no objections to approval of Minoxidil Orifarm, from a non-clinical and clinical point of view. The absence of bioequivalence studies is acceptable. Therapeutic equivalence can be concluded based on quality data. The product information is acceptable. The benefit/risk is considered positive, and the application is therefore recommended for approval.

V. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

V.1 List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

Post approval commitments
N/A

V.2 List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

N/A

V.3 Summary of Product Characteristics (SmPC)

The approved SmPC is available on the Swedish MPA website.

V.4 Package Leaflet (PL)

V.4.1 Package Leaflet

The approved PL is available on the Swedish MPA website.

V.4.2 Assessment of User Testing

A user consultation with target patient groups on the package information leaflet (PL) has been performed on the basis of a bridging report making reference to:

- Rogaine 50 mg/g, kutant skum (SE/H/1173/001) for content and
- Kaliumklorid Orifarm 750 mg Depottabletter (DK/H/2347/001) for layout.

The bridging report submitted by the applicant has been found acceptable.

VI. STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

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