LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Glycolan
glycerol

Asp no: 2020-0305

Applicant: Evolan Pharma AB

This module reflects the scientific discussion for the approval of Glycolan. The procedure was finalised on 2021-04-13. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Glycolan, 200 mg/g, Cream, is submitted according to Article 10(3) of Directive 2001/83/EC. The applicant, Evolan Pharma AB applies for a marketing authorisation in Sweden through a National Procedure.

The active substance is not considered a new active substance.

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Miniderm 20% cream, authorised in Sweden since 2000, with ACO Hud Nordic AB as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

For recommendations to the marketing authorisation not falling under Article 21a/22 of Directive 2001/83/EC 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 the non-clinical aspects

Pharmacodynamic, pharmacokinetic and toxicological properties of glycerol are well known. As glycerol 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.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

For locally applied products, bioequivalence is generally not a suitable way to show therapeutic equivalence, since plasma levels are not relevant for local efficacy, although they may play a role regarding safety. The applicant has not submitted any pharmacokinetic studies. Thus, it is not known if the systemic exposure is different following topical application of the applied product compared to the reference product. However, since the pharmaceutical composition is assessed as essentially similar to that of the reference product (with the exception of the pH-regulating substances), it is not considered likely that the systemic exposure should differ considerably. The absence of pharmacokinetic studies is acceptable.

IV.2 Discussion on the clinical efficacy and safety

The efficacy and safety of glycerol in the treatment of dry skin of different origin is considered well known. No formal clinical efficacy and safety study with Glycerol Evolan 20% cream has been performed. The product can be approved from a clinical perspective based on pharmaceutical similarity to Miniderm 20% cream. A similar clinical efficacy and safety profile of Glycerol Evolan 20% cream and Miniderm 20% cream is anticipated.

IV.3 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 Glycolan cream.

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 1.0 signed 07-Nov-2017 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 Canoderm 5 % cream, SE/H/556/01/P/01 and Natriumklorid Evolan 500 mg capsules, national procedure, Dnr 5.4.1-2014-5246. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The benefit/risk ratio is considered positive and Glycolan, 200 mg/g, Cream is recommended for approval.

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

Glycolan, 200 mg/g, Cream was approved in the national procedure on 2021-04-13.

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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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