LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Glycerol NET
(glycerol)

2018-0835

This module reflects the scientific discussion for the approval of Glycerol NET. The procedure was finalised on 2018-12-14. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Glycerol NET, 200 mg/g, cream, is a hybrid applications made according to Article 10(3) of Directive 2001/83/EC. The applicant, Evolan Pharma AB applies for marketing authorisations in Sweden through a National Procedure.

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

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.

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 with regard to 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, 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 aspects

Pharmacodynamics
Glycerol is considered a well-known constituent of moisturizing creams. The mode of action of glycerol in Glycerol NET 200 mg/g cream and Glycerol NET is the same as in the reference product Miniderm 20% cream. The water-binding ability of glycerol contributes to normalization of dry skin.

Clinical efficacy
The efficacy of glycerol in the treatment of dry skin of different origin is considered well known. The pharmaceutical composition of Glycerol 200 mg/g cream Glycerol NET is assessed as essentially similar to Miniderm 20% cream, and the clinical efficacy will therefore be the similar for the two medicinal products.

Clinical safety
The safety profile of glycerol 20% when used in moisturizing creams is considered well known. The labelling of clinical safety in the SmPC of Miniderm 20% cream is considered to adequately reflect the safety data available. The same labelling is used for Glycerol NET 200 mg/g cream and Glycerol NET.

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 Glycerol NET.

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 and Natriumklorid Evolan 500 mg capsules. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the product, Glycerol NET is found adequate. There are no objections to approval of the product from a non-clinical point of view. From a clinical point of view, the application is overall considered accepted. For this hybrid application no bioequivalence, efficacy or safety studies are required. The pharmaceutical composition of the product is not completely identical with the reference product Miniderm cream, but very similar, the marginal difference was assessed of no clinical relevance. Therefore, Glycerol NET received the same labelling as the reference product. The product information is acceptable.

The benefit/risk ratio is considered positive and Glycerol NET 200 mg per 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

Glycerol NET 200 mg/g cream was approved in the national procedure on 2018-12-14.

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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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