

**EUMOCREAM 25%W/W
PL 10949/0368**

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EUMOCREAM 25%W/W
PL 10949/0368

LAY SUMMARY

The MHRA granted Glaxo Wellcome UK Limited a Marketing Authorisation (licence) for the medicinal product Eumocream 25% w/w (PL 10949/0368). This is a General Sales List medicine (GSL).

Eumocream 25%w/w is a non-steroid hydrating cream used to moisture dry sensitive itchy skin and used in the management of dry or flaky skin conditions such as eczema and dermatitis.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of taking Eumocream 25% w/w outweigh the risks; hence a Marketing Authorisation has been granted.

**EUMOCREAM 25%W/W
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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Eumocream 25% w/w (PL 10949/0368) on 3rd April 2007. The product is a General Sales List (GSL) product for sale to the general public.

This application was submitted as an abridged application according to Article 10a of Directive 2001/83/EC, as amended, and was submitted with a complete bibliography in support of well-established use.

The product contains the active ingredient glycerol; and is used to moisture dry sensitive itchy skin and used in the management of dry or flaky skin conditions such as eczema and dermatitis. When the product is applied to the skin it acts as an emollient and humectant.

As the active ingredient is a drug substance for which safety and efficacy is well established it is not considered necessary to conduct additional non-clinical or clinical studies to support this application.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE (GLYCEROL)

rINN: Glycerol

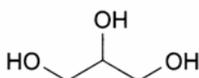
Chemical Name: Propane-1,2,3-triol

Physical form: Syrupy liquid, unctuous to the touch, colourless or almost colourless, clear, very hygroscopic.

Molecular formula: C₃H₈O₃

Molecular weight: 92.1

Structure:



An appropriate specification based on the European Pharmacopoeia has been provided.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. On receipt, the finished product manufacturer test for compliance with the Ph. Eur. Typical certificates of analysis have been provided and are satisfactory.

The active substance is stored in appropriate packaging. The specifications and typical analytical test reports are provided and are satisfactory.

Batch analysis data are provided and comply with the proposed specification.

Appropriate stability data have been generated that support the retest period for the drug substance when stored in the proposed packaging.

DRUG PRODUCT

Other ingredients

Other ingredients consist of pharmaceutical excipients, namely glycerol monostearate 40-55, cetostearyl alcohol, beeswax substitute-6621, arlachel 165, dimeticone, chlorocresol, sodium citrate, citric acid monohydrate and purified water. All excipients used comply with their respective European Pharmacopoeial monograph; with the exception of beeswax substitute-6621, arlachel 165 which complies with in-house specifications which are satisfactory.

Satisfactory certificates of analysis have been provided for all excipients.

None of the excipients used are novel or contain material of animal or human origin.

Manufacture

A full description and a detailed flow-chart of the manufacturing method has been provided. A Good Manufacturing Practice (GMP) certificate has been provided for the manufacturing site.

A satisfactory batch formula has been provided for the manufacture of the product. The manufacturing process has been validated and appropriate in-process controls are applied. Process validation has been carried out on three batches of the product and the results were satisfactory.

Finished product specification

The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

Container Closure System

Product is packaged in membrane sealed, collapsible, aluminium tubes, coated internally with epoxy resin based lacquer. The tubes are sealed with a latex band sealant and a closure composed of polypropylene and polyethylene. The tubes are further packed into cardboard cartons. Specifications and certificates of analysis for all packaging types used have been provided and are satisfactory. The product is packaged in pack sizes of 30g and 100g tubes.

Stability

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 3 years has been set, which is satisfactory. Storage conditions are “Do not store above 25 degrees” and “Do not freeze”.

Summary of Product Characteristics

This is satisfactory.

Patient Information Leaflet

The applicant has instead provided a combined label-leaflet. This is acceptable. The marketing authorisation holder has provided a commitment to update the marketing authorisation with a package leaflet in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups, no later than 1st July 2008.

Conclusion

It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for an application of this type.

CLINICAL ASSESSMENT

CLINICAL BACKGROUND

Glycerol is an osmotic dehydrating agent with hygroscopic and lubricating properties. Glycerol has a wide range of applications in pharmaceutical formulation; these include its use as a vehicle and solvent, as a sweetening agent, as a preservative in some liquid medications, as a plasticiser in tablet film-coating, and as a tonicity adjuster. It is often included in topical preparations such as eye drops, creams, and lotions as a lubricant and also for its moisturising properties since, when absorbed, its hygroscopic action may enhance moisture retention. Ear drops for the removal of ear wax often contain glycerol as a lubricating and softening agent.

Glycerol has also been given by mouth or intravenously to reduce intracranial pressure.

Glycerol may be used rectally as suppositories or a solution in single doses to promote faecal evacuation in the management of constipation. Glycerol is commonly classified as an osmotic laxative but may act additionally or alternatively through its local irritant effects; it may also have lubricating and faecal softening actions.

Glycerol is used as a demulcent in cough preparations.

INDICATIONS

This product is indicated for the management of dry or flaky skin conditions which may also be pruritic such as eczema or dermatitis.

DOSE AND DOSE REGIMEN

For topical application to the skin.

Adults, the elderly, infants, babies and children:

The cream should be applied to the affected areas as often as required.

LEGAL STATUS

GSL

CLINICAL PHARMACOLOGY

PHARMACOKINETICS

Eumo Cream is for topical use only. There are no pharmacokinetic data for this product.

PHARMACODYNAMICS

ATC Code: D02AX

When this product is applied to the skin it acts as an emollient and humectant.

CLINICAL EFFICACY

The applicant has not provided new clinical efficacy data. The bibliographic support is mostly based on the use of emollients for dry skin conditions. There were few

studies done with glycerol. However despite the lack of strong clinical evidence, the use of these types of drugs in the management of dry skin conditions is widely accepted.

CLINICAL SAFETY

No formal safety data have been provided for this application and none are required.

EXPERT REPORTS

The clinical expert report is written by a medically qualified doctor and is satisfactory.

PRODUCT LITERATURE

SUMMARY OF PRODUCT CHARACTERISTICS

This is satisfactory.

PATIENT INFORMATION LEAFLET

A PIL has not been provided. The applicant has instead provided a combined label-leaflet. This is acceptable.

PIL should be in line with the applicant's SPC

APPLICATION FORM

This is satisfactory.

RECOMMENDED CONDITIONS FOR MARKETING AUTHORISATION

The bibliographic evidence provided to support the use of glycerol on dry skin conditions, is very limited. However, glycerol, as an emollient, may be used for dry skin conditions. Despite the lack of good quality randomised controlled trials, emollients are a well-established therapy for dry skin conditions. After a consultation with one of the MHRA Clinical Experts, it was agreed that glycerol can be used for dry skin conditions in children and adults,

A product license may be granted for this product.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT**QUALITY**

The important quality characteristics of Eumocream 25% w/w are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

No new or unexpected safety concerns arise from this application.

The SPC and combined label-leaflet are satisfactory.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with glycerol is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

EUMOCREAM 25%W/W
PL 10949/0368

STEPS TAKEN FOR ASSESMENT

| | |
|---|--|
| 1 | The MHRA received the marketing authorisation application on 26 th November 2004. |
| 2 | Following standard checks and communication with the applicant the MHRA considered the applications valid on 31 st July 2005. |
| 3 | Following assessment of the applications the MHRA requested further information relating to the quality dossiers on 20 th February 2006 and 28 th November 2006. |
| 4 | The applicant responded to the MHRA's requests, providing further information on 17 th October 2006 and 5 th December 2006 for the quality sections. |
| 5 | The applications were determined on 3 rd April 2007. |

EUMOCREAM 25%W/W**PL 10949/0368****STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

| Date submitted | Application type | Scope | Outcome |
|-----------------------|-------------------------|--------------|----------------|
| | | | |
| | | | |
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| | | | |
| | | | |

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Eumocream 25% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycerol 25% w/w

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream

Smooth, white cream

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

This product is indicated for the management of dry or flaky skin conditions which may also be pruritic such as eczema or dermatitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For topical application to the skin.

Adults, the elderly, infants, babies and children:

The cream should be applied to the affected areas as often as required.

4.3 CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Avoid contact with the eyes, as the product may cause irritation to the epithelial cells of the cornea.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

None stated

4.6 PREGNANCY AND LACTATION

Animal studies are insufficient with respect to effects on pregnancy, foetal development, parturition or postnatal developments. The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None stated

4.8 UNDESIRABLE EFFECTS

Hypersensitivity reactions have been rarely reported; they usually consist of localised skin reactions.

4.9 OVERDOSE

Eumocream is of low toxicity. If accidental ingestion occurs, conservative treatment only is required.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC Code: D02AX

When this product is applied to the skin it acts as an emollient and humectant.

5.2 PHARMACOKINETIC PROPERTIES

Eumocream is for topical use only. There are no pharmacokinetic data for this product.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Glycerol monostearate 40-55

Cetostearyl alcohol

Beeswax substitute 6621 (Paraffin wax, Vegetable Stearic acid, Prime Yellow
Camauba wax)

Arlacel 165 (Glycerol Monostearate, Polyoxyethylene 100 Stearate)

Dimeticone

Chlorocresol

Sodium citrate

Citric acid monohydrate

Purified water

6.2 INCOMPATIBILITIES

Not applicable

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25 °C. Do not freeze.

6.5 NATURE AND CONTENTS OF CONTAINER

Collapsible aluminium tube internally lacquered with an epoxy coat, with a latex
band and a wadless polypropylene cap.

30 g and 100 g tubes.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

None stated

7 MARKETING AUTHORISATION HOLDER

Glaxo Wellcome U.K. Limited

Stockley Park West

Uxbridge

Middlesex

UB11 1BT

Trading as: GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K.

8 MARKETING AUTHORISATION NUMBER(S)

PL 10949/0368

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

03/04/2007

10 DATE OF REVISION OF THE TEXT

03/04/2007

PATIENT INFORMATION LEAFLET/LABEL
PL 10949/0368

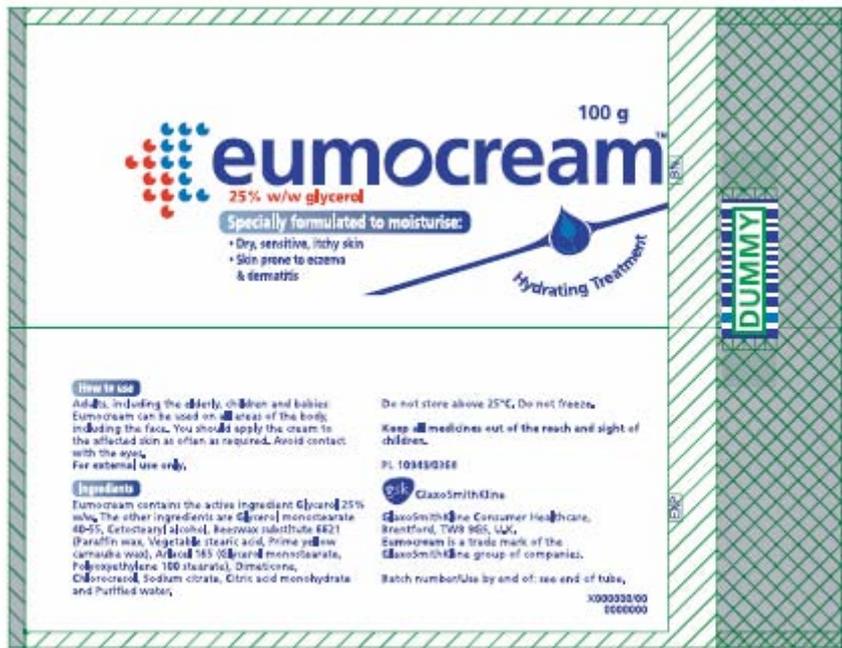
LABEL-
30g



CARTON



**LABEL-
100g**



CARTON

