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LAY SUMMARY

The MHRA today granted Ego Pharmaceuticals (UK) Limited a Marketing Authorisation (licence) for the medicinal product QV Cream (PL 18278/0007). This is a general sales licence (GSL) for use as an emollient for the symptomatic relief of dermatological conditions associated with dry skin, including atopic dermatitis, ichthyosis, xerosis, pruritis, eczema, psoriasis, and exposure to sun, wind and cold weather.

QV Cream contains the active ingredients glycerol, light liquid paraffin and white soft paraffin.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using QV Cream outweighed the risks, hence a Marketing Authorisation has been granted.
SCIENTIFIC DISCUSSION

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Introduction ........................................ Page 4
Pharmaceutical assessment ......................... Page 5
Preclinical assessment ............................. Page 9
Clinical assessment (including statistical assessment) ........................................ Page 10
Overall conclusions and risk benefit assessment ........................................ Page 11
INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product QV Cream to Ego Pharmaceuticals (UK) Limited (PL 18278/0007) on 24th August 2006. The product has a general sales licence (GSL).

The application was submitted as an abridged application according to Article 10a of Directive 2001/83/EC, a bibliographic application.

The product contains the active ingredients glycerol, light liquid paraffin and white soft paraffin and is indicated for the symptomatic relief of dermatological conditions associated with dry skin, including atopic dermatitis, ichthyosis, xerosis, pruritis, eczema, psoriasis, and exposure to sun, wind and cold weather.

All active substances act as emollients.
PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE (GLYCEROL)

RINN  Glycerol

Structure:

\[
\text{HO} \quad \text{H} \quad \text{OH} \quad \text{OH}
\]

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis. A comprehensive risk assessment has been performed on the active substance such that a certificate of suitability is not required and it can be assumed that glycerol produced by Symex is not susceptible to TSE.

An appropriate specification is provided for the active substance glycerol.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Appropriate proof of structure has been supplied for the active pharmaceutical ingredient.

All potential known impurities have been identified and characterised.

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

The container used for storage of the active substance is satisfactory.

Appropriate stability data have been generated and no indication of instability seen. The data support a retest period of 12 months.

DRUG SUBSTANCE (WHITE SOFT PARAFFIN)

RINN  White Soft Paraffin, White Petroleum Jelly

Chemical name:  Petrolatum
Other name:  Bentley Wax 1832 (BW 1832)
Physical form:  Semi-solid
Molecular formula:  C\text{20 to C\text{50}} - mixture of straight and branched chain paraffin’s.
Molecular weight:  500 (mass average molecular weight)
Stereoisomerm/chirality:  No
Polymorphism:  No

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate
specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance white soft paraffin that complies with the current Ph Eur/BP monographs.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

All potential known impurities have been identified and characterised.

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

The container used for storage of the active substance is satisfactory.

Appropriate stability data have been generated and no indication of instability seen. The data support a retest period of 24 months.

**DRUG SUBSTANCE (LIGHT LIQUID PARAFFIN)**

INN: Light Liquid Paraffin  
Other name: Paraffinium perliquidium  
Physical form: Colourless transparent, oily free from fluorescence in daylight  
Molecular formula: A mixture of liquid saturated hydrocarbons.  
Chemical name: Refined Mineral Oil  
Chemical formula: Saturated hydrocarbons with 2gaussian distribution” in the range C17 to C30. There are 500 to 2000 isomers of the structural formula – individual description is not possible.  
Other names: Marcol 82, E-Marcol 82, Marcel N 82, Vaseline Oil, Codex Oil, medicinal White Oil, White Mineral Oil, Food Grade Oil White Oil.  
Physical form: Liquid Oil  
Stereoisomer/chirality:NA  
Polymorphism: NA  
Structure: NA

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance light liquid paraffin that complies with the current Ph Eur/BP monographs.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

All potential known impurities have been identified and characterised.
Batch analysis data are provided that comply with the proposed specification.

The container used for storage of the active substance is satisfactory.

Appropriate stability data have been generated and no indication of instability seen. The data support a retest period of 24 months.

**DRUG PRODUCT**

**Other ingredients**

Other ingredients consisted of pharmaceutical excipients cetostearyl alcohol, glyceryl monostearate (self-emulsifying), squalane, stearic acid, water purified, dichlorobenzyl alcohol, macrogol cetostearyl ether, glyceryl monostearate 40-55, macrogol lauryl ether, methyl parahydroxybenzoate E218, and dimeticone. With the exception of dichlorobenzyl alcohol (which complies with suitable in-house specifications), all excipients used comply with their respective Ph Eur monograph. The specification for Laureth-3 complies with that for macrogol lauryl ether.

Satisfactory certificates of analysis have been provided for all excipients.

With the exception of stearic acid and squalane, none of the excipients used contain material of animal or human origin. Squalane is obtained from shark liver oil and as such is exempt from the EU guidance on TSE. Stearic acid is derived from the same process as used to make the active substance glycerol. Therefore, the process is suitably vigorous and complies with Ph Eur requirements.

**Manufacture**

A satisfactory description and flow-chart of the manufacturing method has been provided. In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out on full-scale batches of the product. The results appear satisfactory.

**Bioavailability**

There are no bioavailability studies as the product is intended for topical application. As the active ingredient does not require systemic absorption for its effect. Consequently, this omission is acceptable.

**Finished product specification**

The finished product specification is satisfactory. Test methods have been described and have been adequately validated as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

**Container Closure System**

Specifications and Certificates of Analysis for the primary packaging material have been provided. These are satisfactory. All primary packaging is controlled to Ph Eur standards. The finished product is presented in pack sizes of 15 and 100grams (for product packaged in the laminated tube with polypropylene screw cap), and 250 and 500grams for product packaged in the high density polyethylene jar with the polypropylene cap.
Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 36 months (24 months for the 250gram product size) has been set with the precaution “Do not refrigerate”, which is satisfactory.

Conclusion
It is recommended that a Marketing Authorisation is granted for this application.
**PRECLINICAL ASSESSMENT**

As this is a bibliographic application containing active substances (glycerol, white soft paraffin, light liquid paraffin) that have been used in products for over 20 years, it was not considered necessary to perform a preclinical assessment.
CLINICAL ASSESSMENT

1. INDICATIONS
QV Cream is indicated for the symptomatic relief of dermatological conditions associated with dry skin, including atopic dermatitis, ichthyosis, xerosis, pruritis, eczema, psoriasis, and exposure to sun, wind and cold weather.

The indications are satisfactory for a product of this type.

2. DOSE & DOSE SCHEDULE
For cutaneous (topical) administration only.

QV Cream should be applied as required to the affected skin area, as often as required, especially after showering, bathing, shaving, exposure to harsh climatic conditions and at night.

3. TOXICOLOGY
No new data submitted and none are required for this application.

4. CLINICAL PHARMACOLOGY
No new data submitted and none are required for this application.

5. EFFICACY
No new data submitted and none are required for this application.

6. SAFETY
No data submitted.

7. EXPERT REPORTS
An expert report by an appropriately qualified physician

8. PATIENT INFORMATION LEAFLET (PIL)
Satisfactory.

9. LABELLING
Satisfactory.

10. APPLICATION FORM (MAA)
Satisfactory.

11. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
Satisfactory.

12. MEDICAL CONCLUSION
It is recommended that a Marketing Authorisation be granted.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of QV Cream 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 studies were conducted. The preclinical data submitted have not revealed any evidence of potential risks to human health from use of QV Cream.

EFFICACY
No new or unexpected safety concerns arise from this application.

The SPC and PIL are satisfactory and consistent with that for the reference products.

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 the active substances is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.
**STEPS TAKEN FOR ASSESSMENT**

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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 12th October 2000</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 6th November 2000</td>
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<tr>
<td>3</td>
<td>Additional clinical information was requested on 19th December 2000 and additional pharmaceutical information was requested on 22nd May 2001</td>
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<td>4</td>
<td>Additional pharmaceutical and clinical information was provided on 12th November 2002</td>
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<td>5</td>
<td>Further pharmaceutical information was requested from the applicant on 17th February 2003, 17th June 2003, 28th May 2004 and 18th January 2006</td>
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<tr>
<td>6</td>
<td>Further pharmaceutical information was provided on 8th May 2003, 18th August 2003, 18th October 2005 and 17th July 2006</td>
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<td>7</td>
<td>The application was determined on 24th August 2006</td>
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## STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT
   QV Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
   Glycerol 10 % w/w
   Light Liquid Paraffin 10 % w/w
   White Soft Paraffin 5 % w/w.
   For excipients, see 6.1

3. PHARMACEUTICAL FORM
   Cream.
   White to off-white cream

4. CLINICAL PARTICULARS
   4.1. Therapeutic Indications
   For the symptomatic relief of dermatological conditions associated with dry skin including:
   • Atopic dermatitis
   • Ichthyosis
   • Xerosis
   • Pruritis
   • Eczema
   • Psoriasis
   • exposure to sun, wind and cold weather.

   4.2. Posology and Method of Administration
   Administration:
   For cutaneous (topical) administration only.

   Dosage:
   QV Cream should be applied as required to the affected skin area, as often as required, especially after showering, bathing, shaving, exposure to harsh climatic conditions and at night.

   4.3. Contra-indications
   Hypersensitivity to any of the ingredients of the preparation.
   Seborrhoeic dermatitis

   4.4. Special Warnings and Precautions for Use
   For external use only.
   QV Cream contains Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)
   QV Cream contains Methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

   Avoid contact with the eyes. Upon accidental contact, flush with clean water.
   To avoid further irritation of sensitive skin do not use soap on the affected area.

   If the condition does not improve or is aggravated, discontinue use and consult the doctor.

   4.5. Interactions with other Medicaments and other forms of Interaction
   No known interactions.

   4.6. Pregnancy and Lactation
   There is no evidence of the safety of QV Cream in human pregnancy and lactation. However, the constituents of the preparation have been in wide use for many years without apparent ill consequences.
4.7. Effects on Ability to Drive and Use Machines
Not applicable.

4.8. Undesirable Effects
No known undesirable effects.

4.9. Overdose
No case of overdose has been reported

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic Properties
Pharmacotherapeutic group: Other emollients and protectives, ATC Code: D02AX
The formulation contains light liquid paraffin 10% w/w and white soft paraffin 5% w/w. These ingredients are primarily responsible for the emollient characteristics of the product i.e. they form a layer over the skin that retards the loss of water through the stratum corneum. It is the moisture that is retained as a result of this occlusive effect that keeps the skin soft and pliable.

The formulation also contains glycerol 10% w/w which is known to have a conditioning effect on the skin. The exact nature of the mechanism of action of glycerol is not clear but is probably due to its hygroscopic nature so that glycerol absorbed by the skin would thus augment the role of the skin’s natural humectant in retaining moisture to keep skin pliable.

The chosen combination of ingredients imparts a soft, smooth feeling to the skin. Patient acceptability is an important consideration, since a product that feels comfortable to use will encourage the patient to use it frequently as required.

5.2. Pharmacokinetic Properties
Not applicable. For local application only.

5.3. Preclinical Safety Data
The actives are a well-established emollient remedy. They have been safely and effectively used in topical applications for a number of decades. No adverse effects have been reported

6. PHARMACEUTICAL PARTICULARS
6.1. List of Excipients
Cetostearyl alcohol
Dimeticone
Squalane
Stearic acid
Self-emulsifying glyceryl monostearate
Macrogol cetostearyl ether
Macrogol lauryl ether
Glyceryl monostearate
Methyl parahydroxybenzoate (E218)
Dichlorobenzyl alcohol
Purified water

6.2. Incompatibilities
Not Applicable

6.3. Shelf Life
Three years at 30°C for: 100g laminated tubes, 500g HDPE jars and 15g laminated tubes.
Two years at 30°C for: 250g HDPE jars.
6.4. Special Precautions for Storage
Do not refrigerate

6.5. Nature and Contents of Container
100g laminated tube, with an HDPE head and polypropylene screw cap.
250g and 500g HDPE jars fitted with polypropylene lids

Sample pack:
15g laminated tube with an HDPE head and polypropylene screw cap

6.6. Instruction for Use/Handling
No special requirements

7. MARKETING AUTHORISATION HOLDER
Ego Pharmaceuticals (UK) Limited,
15 Windsor Park, 50 Windsor Avenue,
Merton,
London SW19 2TJ
United Kingdom.

8. MARKETING AUTHORISATION NUMBER
PL 18278/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
24/08/2006

10 DATE OF REVISION OF THE TEXT
24/08/2006
QV CREAM, Patient Information Leaflet

<table>
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Patient Information Leaflet

**QV Cream**

*(Glycerol, Light Liquid Paraffin, White Soft Paraffin)*

Please read this leaflet carefully before you start to use QV Cream as it has been prepared to tell you about the product and to help you use it correctly. However, it does not contain all the available information about QV Cream, so if you have any further questions, please ask your doctor or pharmacist.

Please keep this leaflet in a safe place as you may wish to look at it again while you are using QV Cream.

The name of your product is QV Cream

QV Cream is a white to off white cream for use only on the skin. The active ingredients are Glycerol 10%, Light Liquid Paraffin 10% and White Soft Paraffin 5%.

The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, dimeticone, glyceryl monostearate, glyceryl monostearate self emulsifying, macrogol lauryl ether, squalane, stearic acid, purified water, methyl parahydroxybenzoate (E216) and dichlorobenzyl alcohol.

pH 6 : The pH of your skin is pH 6. QV Cream is manufactured at this pH to be mild and gentle on the skin.

QV Cream is free from lanolin, perfume and colour to avoid further irritation to people who may be sensitive to these ingredients.

QV Cream is available in 100 g tubes and in 250 g and 500 g jars.

**About QV Cream**

The active ingredients in QV Cream belong to a group of medicines known as moisturisers, which have been found to be effective in reducing the dryness of the skin and protecting the skin.

Light liquid paraffin and white soft paraffin form a protective layer over the skin surface which slows down the loss of water. The retention of this water keeps the skin soft and pliable.

Glycerol is a humectant. It has a conditioning effect on the skin by increasing the amount of water retained by the skin.

**Marketing Authorisation Holder**
Ego Pharmaceuticals (UK) Limited,
15 Windsor Park,
London SW19 2TJ.
United Kingdom
PL 16278 / 0007

**Manufacturer**
Crawford Healthcare Limited,
Cheshire House,
104 Main Road, Goostrey,
Cheshire, CW4 8JP
United Kingdom

**What is QV Cream for?**
QV Cream is recommended to help relieve dry skin in a wide range of dry skin conditions such as: psoriasis (inflammation of the skin), ichthyosis (scaly skin), pruritis (itchy skin), xerosis (dry skin), dermatitis (changes in the skin surface).
QV Cream is especially recommended in conditions such as eczema, dermatitis and psoriasis and exposure to the sun, wind and cold weather.

**Before you use QV Cream**
QV CREAM. Patient Information Leaflet

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Before you use QV Cream, please note;

Important Information about some of the ingredients of QV Cream: QV Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and methyl parahydroxybenzoate (E218) which may cause allergic reactions, possibly delayed.

Check the list of ingredients stated above. If you are sensitive (have allergies) to any of them do not use this product.

If you have been told by your doctor that you have seborrhoeic dermatitis (dry skin that is very oily) do not use QV Cream

Pregnancy, breast feeding: If you are breast feeding or pregnant or are thinking of starting a family, please talk to your doctor or pharmacist before starting QV Cream

Driving and using machinery: QV Cream will not affect your ability to drive or operate machinery.

Taking other medicines: Please inform your doctor or pharmacist if you are using or taking any other medicines or creams, even those not prescribed.

If you are not sure about using QV Cream then please talk to your doctor or pharmacist.

Advice When Using QV Cream

- Keep the QV Cream away from the eyes. If it accidentally gets into the eyes, flush them with clean water.
- As soap can irritate skin, you may benefit from using a soap substitute rather than ordinary soap on dry areas of skin

If your skin problem becomes worse or you have a reaction, stop using QV Cream and tell your doctor or pharmacist immediately.

How to Use QV Cream

For use on the body, face and hands,

For External Use Only

QV Cream should be applied as required, especially after showering, bathing, shaving or exposure to harsh weather conditions and at night.

- First wash and dry the affected areas.
- Apply the cream with clean hands to the affected area of the skin.
- Apply to the skin, rubbing it well in until it is not visible on the skin surface.
- Replace the cap after use.
- If your skin problem becomes worse, talk to your doctor or pharmacist.
- Avoid contact with eyes.

QV Cream can soften and protect skin before or after bathing or showering. If you have dry or sensitive skin do not use ordinary soap as this will dry it further.
**QV CREAM, Patient Information Leaflet**

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**After Using QV Cream**

QV Cream is very effective and most people do not usually have any problems. If you experience any irritation or any other unwanted effects, then stop using the cream and tell your doctor.

QV Cream may not work immediately, however, if your condition does not improve you should tell your doctor.

If you follow the instructions for use, it should not be possible to use too much. If QV Cream is accidentally swallowed, you should contact your doctor immediately.

*If you are not sure about using QV Cream then please talk to your doctor or pharmacist.*

**Storing QV Cream**

- Always replace the cap after using QV Cream to keep it as clean as possible during use.
- Do not refrigerate.
- If the ‘expiry date’, on the label has passed, stop using QV Cream and dispose of it safely, such as by giving it to your pharmacist.
- You should never give your QV Cream to anyone else to use, even if they appear to have the same symptoms as you.
- Always keep QV Cream in a safe place out of the reach and sight of children.

**Further Information**

Further information is available from your doctor and pharmacist

**Date of preparation of leaflet** June 2006, version 7
15 Gram Pack

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<th>QV CREAM 15G TUBE LABEL</th>
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The batch number and expiry date are embossed on the crimp, as stated on the label.
The batch number and expiry date are printed on the base of the carton, as stated on the label.
100 Gram Pack

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QV CREAM 100G TUBE LABEL

The batch number and expiry date are embossed on the crimp of the tube, as stated on the label.
The batch number and expiry date are printed on the base of the carton, as stated on the label.
250 Gram Pack

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<th>QV CREAM, CARTON for 250g JAR</th>
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The batch number and expiry date are printed on the side of the carton, as stated on the label.
UKPAR QV Cream

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The batch number and expiry date are printed on the base of the jar, as stated on the label.
The batch number and expiry date are printed on the base of the carton, as stated on the label.
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<th>UKPAR QV Cream</th>
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**QV CREAM, 500g JAR**

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The batch number and expiry date are printed on the base of the carton, as stated on the label.