IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0863/002/001
Case No: 2038246

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ego Pharmaceuticals (UK) Limited

15 Windsor Park, **50 Windsor Avenue**, **Merton**, **London SW19 2TJ**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Q.V. Skin Cream

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **07/08/2007** until **08/01/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Q.V. Skin Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycerol	10	% w/w
Paraffin – Light Liquid	10	% w/w
Paraffin – Soft White	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
- Dry skin conditions associated with:
  - Dermatitis
  - Eczema
  - Psoriasis
  - exposure to sun, wind and cold weather.

4.2 Posology and method of administration

Administration:

For cutaneous (topical) administration only.

Dosage:

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

4.3 Contraindications

Hypersensitivity to any of the ingredients of the preparation.
Use in patients with seborrhoeic dermatitis.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. Upon accidental contact, flush with clear water.
The cream is for external use only.
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 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.6 Pregnancy and lactation

There is no evidence of the safety of Q.V. Skin Cream in human pregnancy and lactation, 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

Not applicable (topical preparation).

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The formulation contains light liquid paraffin Ph. Eur. (10% w/w) and soft white paraffin BP (5% w/w). These ingredients are primarily responsible for the emollient characteristics of the product i.e. it forms 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 of soft white paraffin that keeps the skin soft and pliable.

The chosen combination of ingredients also impart a soft, smooth feeling to the skin. Patient acceptability is an important consideration, a product that feels comfortable to use will encourage the patient to use it frequently as required. The formulation also contains glycerol Ph.Eur (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.

5.2 Pharmacokinetic properties

For local application only.

5.3 Preclinical safety data

The constituents of the preparation have been in widespread use for many years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl Alcohol
Dimethicone
Squalane
Stearic Acid
Glyceryl Monostearate Emulsifying
Cetomacrogol 1000
Laureth 3 (Lauromacrogol 150)
Glyceryl Monostearate
Methyl hydroxybenzoate
Dichlorobenzyl Alcohol
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The product has a shelf life of three years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

100g laminated tube consisting of a 7 layer LDPE, paper, aluminium foil and ethylene copolymer laminate body, HDPE head and polypropylene screw cap. The tubes are individually packed into cartons then shrink wrapped in units of 6.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

PA 863/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th February 1998

Date of last renewal: 9th January 2003

10 DATE OF REVISION OF THE TEXT

July 2007