IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0863/001/001
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 Lotion

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 Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Soft White Paraffin 5% w/w.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cutaneous Solution.

White to off-white solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of dermatological conditions associated with dry skin including:

- Ichthyosis
- Pruritis hiemalis
- 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 lotion should be applied as required to the affected skin area, especially after showering, bathing, shaving 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 Lotion in human pregnancy and lactation, but 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).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The formulation contains soft white paraffin BP (5% w/w) which is 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 formulation also contains glycerol Ph.Eur (5% 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

No data is supplied given the widespread use of the constituents of the preparation for many years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

C12-15 Alkyl benzoate
Carbomer
Cetomacrogol 1000
Cetostearyl alcohol
Dichlorobenzyl Alcohol
Dimethicone
Glycerol
Glyceryl Monostearate
Methyl hydroxybenzoate
Propyl hydroxybenzoate
Purified water
Steareth - 2
Triethanolamine

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The product has a shelf life of two years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

White pre-printed 200g HDPE bottles fitted with a neutral polypropylene plug and white polypropylene pip-seal screw caps.

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 863/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th January 1998

Date of last renewal: 9th January 2003

10 DATE OF REVISION OF THE TEXT

July 2007