IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0863/003/002
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

Egoderm Ointment

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 **15/10/2008**.

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

Egoderm Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ichthammol	1	% w/w
Zinc Oxide	15	% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment
Pale fawn coloured ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of itching and inflammation associated with the following conditions:

- Dermatitis,
- Eczema,
- Tender, itchy, scratched or broken skin rashes,
- Eruptions in the napkin area, due to various causes,
- Anal or genital itching,
- Minor cold sores.

4.2 Posology and method of administration

Administration:

For cutaneous (topical) administration only.

Dosage:

The ointment should be applied to the affected skin area 2 to 4 times daily.

4.3 Contraindications

Known hypersensitivity to the ingredients of the preparation.
Oily skin.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. Upon accidental contact, flush with clear water.
The ointment is for external use only.
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

Use of this product in human pregnancy and lactation has not been investigated, but ichthammol and zinc oxide have been in wide use for many years without apparent ill consequences. No adverse effects have been reported in published literature.

4.7 Effects on ability to drive and use machines

Not applicable - not likely to produce an effect when used as directed.

4.8 Undesirable effects

No known undesirable effects.

4.9 Overdose

Not applicable (topical preparation).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The ointment contains two active ingredients ichthammol 1% w/w and zinc oxide 15% w/w. The mode of action of the ichthammol has not been elucidated, however, it has been in widespread use for many years and is used for the symptomatic relief of pruritus and inflammation. Zinc oxide is a mild astringent and is often used in conjunction with ichthammol for the treatment of a wide variety of skin conditions including ulcers, eczema and psoriasis.

5.2 Pharmacokinetic properties

For local application only.

5.3 Preclinical safety data

Both declared active ingredients have been used in topical applications for many years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethicone
Light liquid paraffin
Glycerol
Glyceryl monostearate
Isopropyl myristate
Methyl hydroxybenzoate [E218]
Polyethylene
Propyl hydroxybenzoate [E216]
Soft white paraffin
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Pre-printed laminate tubes of 25 and 50g packed into pre-printed cartons.

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 863/3/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 October 1998

Date of last renewal: 16 October 2003

10 DATE OF REVISION OF THE TEXT

July 2007