IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0863/006/001
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

Pinetarsol Cutaneous Solution

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 **03/02/2010**.

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

Pinetarsol Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tar 2.3% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
Aqua blue/green, sudsing, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the management of psoriasis and chronic forms of dermatitis and eczema.

4.2 Posology and method of administration

Pinetarsol Solution is intended for addition to water or for use on wet skin as follows:

Bath: Add 15 - 30 ml to a warm to tepid bath (5 ml to a baby's bath or hand basin). Bathe for 5 to 10 minutes once daily, more often in severe cases. Pat skin dry.

Shower: Apply directly to wet skin, leave for a few minutes, then rinse. Pat skin dry.

Small areas: Add 10 ml to 3 litres of cool or iced water. Saturate cotton wool and hold onto area for a few minutes. Pat skin dry.

Patients in bed: Add 10ml to 3 litres of warm water. Sponge the affected areas. Pat the skin dry.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes.
For very inflamed skin, use with water.
Do not use continuously for prolonged periods except under medical direction.
Use only when clearly necessary.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.6 Pregnancy and lactation

Use in pregnancy and lactation has not been investigated, however, tar has been widely used for many years and no adverse effects have been reported in the published literature.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Pine tar may give rise to hypersensitivity reactions.

4.9 Overdose

Not applicable (topical preparation).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antipruritic, ATC code: D04AX.
Pinetarsol Solution is a solution containing 2.3% w/w Tar (pine tar) and 6% w/w triethanolamine lauryl sulphate.
The mode of action of tar 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 in a wide variety of skin conditions.
Triethanolamine lauryl sulphate provides the cleansing action of Pinetarsol Solution.
The product is formulated to have a pH similar to that of skin in order to minimise irritation of tender or inflamed skin.

5.2 Pharmacokinetic properties

Pinetarsol Solution is for external use only.

5.3 Preclinical safety data

No data is presented given the widespread use of Pine tar for many years without reported ill consequence.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dichlorobenzyl alcohol
Lavender Oil
Patent blue V (E131)
Phenethyl Alcohol
Triethanolamine lauryl sulphate
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

100, 200 and 500ml white, opaque, PVC, bottles fitted with wadded polypropylene, screw caps.

200ml white, opaque, PVC, bottles fitted with a wadded, polypropylene screw cap incorporating a spray pump.

1 and 5 litre white, opaque, polypropylene, bottles fitted with wadded polypropylene, screw caps.

Not all pack sizes may be marketed.

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

Avoid contact with the eyes.

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 863/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 February 2000

Date of last renewal: 04 February 2005

10 DATE OF REVISION OF THE TEXT

July 2007