IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0863/007/001
Case No: 2037015

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

MOOV Head Lice 11 %w/w 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 **25/07/2008** until **24/07/2013**.

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

MOOV Head Lice 11% w/w Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active:

Eucalyptus Oil 11.0% w/w

Excipients:

Contains hydrogenated polyoxyl castor oil 20% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.

Pale yellow to yellow, clear solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the eradication of head lice and their eggs.

4.2 Posology and method of administration

Suitable for adults; suitable for children aged 4 years and older.

Paediatric patients:
For use in children aged 4 years and older, only.
MOOV Head Lice Cutaneous Solution is not recommended for use in children under 4 years as the safety in this age group has not been established.

Route of Administration:

For use only on the scalp

Recommended Dosage Schedule:

1. Use on dry hair. Cover eyes with towel.
2. Apply product to the hair behind the ears and the back of the neck first. Then apply to rest of hair. Apply sufficient product to ensure hair is thoroughly wet. The amount used will depend on the length and thickness of hair.
3. Massage into the scalp and hair.
4. Cover all hair, including ears, to the nape of the neck with the shower cap (supplied).
5. Leave on hair for **ten minutes**.
6. Remove cap, shampoo and condition hair as normal.
7. Rinse cap well after use with soap and warm water. Dry thoroughly. The cap can be re-used.

8. Repeat steps 1 to 7 at seven and fourteen days after initial treatment.

A pharmacist or doctor should be contacted if the symptoms persist after three (3) treatments

4.3 Contraindications

Known sensitivity to the ingredients of the preparation.

4.4 Special warnings and precautions for use

Flammable. Avoid contact with flames

Ensure that MOOV Head Lice 11% w/w Cutaneous Solution is used only in an adequately ventilated area.

For external use only. Keep out of the reach and sight of children.

Avoid contact with face. Wash hands after use.

Avoid contact with eyes. If contact does occur, flush immediately with water.

Do not use on excoriated scalp

To be used with caution in patients with asthma as it may aggravate bronchial spasm.

The product is poisonous if ingested. A doctor or casualty department should be contacted at once if MOOV Head Lice 11% w/w Cutaneous Solution is inadvertently swallowed (see section 4.9).

MOOV Head Lice 11% Cutaneous Solution is not recommended for use in children under 4 years as the safety in this age group has not been established.

Contains hydrogenated polyoxyl castor oil which may cause skin reactions.

People who routinely apply MOOV Head Lice 11% w/w Cutaneous Solution may wish to wear gloves to avoid any possible irritation to the hands

4.5 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.6 Pregnancy and lactation

Pregnancy:

Use of this product in human pregnancy and lactation has not been investigated.

Animal studies are insufficient with respect to effects on pregnancy, embryo-fetal development, parturition or postnatal development (see section 5.3). The potential risk for humans is unknown. Caution should be exercised when recommending to pregnant women.

Lactation:

It is unknown whether eucalyptus oil is excreted in human breast milk. The excretion of eucalyptus oil has not been adequately studied in animals, (see Section 5.3). A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with MOOV Head Lice 11% w/w Scalp Solution should be made taking into account the benefit of breast-feeding to the child and the benefit of MOOV Head Lice 11% w/w Scalp Solution therapy to the woman.

4.7 Effects on ability to drive and use machines

Not applicable – not likely to produce an effect when used topically, as directed.

4.8 Undesirable effects

The following undesirable effects were identified in two clinical trials, one with 49 subjects and one with 11 subjects (ie n = 60).
The frequency listed below is defined using the following convention; very common (≥ 1/10) and common (≥ 1/100, <1/10).

Skin & subcutaneous tissue disorders *Very common:* Pain *Common:* Pruritus, skin burning sensation
General disorders and administration site conditions *Common:* Feeling hot

Post-Marketing:

The following adverse events have been reported very rarely (< 10,000 including isolated cases) during post-marketing surveillance (the calculation for the frequency is based on an estimate of patient exposure):

Immune system disorders	Hypersensitivity
Nervous system disorders	Headache
Gastrointestinal disorders	Nausea
Skin and subcutaneous tissue disorders	Pain, skin burning sensation, skin exfoliation, erythema, pruritus, skin reaction, alopecia, lip blister, facial oedema
General disorders and administration site conditions	Application site odour

The classification of side effects conforms to MedDRA requirements

4.9 Overdose

If MOOV Head Lice 11% w/w Cutaneous Solution is swallowed, the active ingredient, eucalyptus oil, is rapidly absorbed from the gastro-intestinal tract causing ataxia, vomiting, abdominal pain and miosis. Increasing severity of intoxication is characterised by drowsiness followed by unconsciousness.

In adults the lowest published lethal dose for eucalyptus oil is 375mg/kg body weight when administered orally, while in children the lowest published toxic dose is 218 mg/kg body weight.

Vomiting should not be induced if MOOV Head Lice 11% w/w Cutaneous Solution if swallowed.

MOOV Head Lice 11% w/w Cutaneous Solution contains 20% methylated spirits.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Eucalyptus oil as formulated in MOOV Head Lice 11% w/w Cutaneous Solution is insecticidal and ovicidal against hea lice. The mechanism of action is not known.

The product is intended for topical application for the treatment of the head lice infestation. The product should be reapplied 7 days and again 14 days after the original treatment to kill any newly hatched lice and to ensure eradication o the infestation.

5.2 Pharmacokinetic properties

For local application only.

Eucalyptus oil is not absorbed significantly following short term topical application and is rapidly eliminated.

5.3 Preclinical safety data

Conventional studies of safety pharmacology, reproductive toxicity and carcinogenicity have not been conducted. However, limited reproductive toxicity data suggest that eucalyptus oil is not teratogenic. Eucalyptus oil did not appear to pass into milk in significant quantities in rats when administered to dams subcutaneously at 500mg/kg/day on days 2 to 6 post-delivery.

The limited published studies on genotoxicity and carcinogenicity suggest that eucalyptus oil is not genotoxic in vitro at concentrations that are not cytotoxic, and that it is not carcinogenic in male mice.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated polyoxyl castor oil

Disodium edetate

Methylated spirit – industrial (contains ethanol)

Tocopherol excipient

Benzyl alcohol

Lemon tea tree oil

Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C.

Keep bottle in the outer carton.

6.5 Nature and contents of container

200ml PET bottle with a polypropylene flip-top screw cap

PVC green shower cap

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Ego Pharmaceuticals (UK) Ltd.,
15 Windsor Park,
50 Windsor Avenue, Merton
London, SW19 2TJ,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA0863/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 25th July 2008

10 DATE OF REVISION OF THE TEXT