

**IRISH MEDICINES BOARD ACT 1995**

**MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998**

**(S.I. No.142 of 1998)**

**PA0471/011/001**

Case No: 2031037

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

**Potters (Herbal Supplies) Ltd**

**1 Botanic Court, Martland Park, Wigan, WN5 0JZ, United Kingdom**

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

**Potter's Skin Clear 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 **18/12/2006** until **29/11/2007**.

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

Potter's Skin Clear Ointment

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Maize Starch	17	% w/w
Sublimed Sulphur	5	% w/w
Zinc Oxide	23	% w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Ointment.

A cream-coloured hydrophobic ointment with a slight aromatic odour.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Mild acne and symptomatic relief of dry (mild) eczema

##### 4.2 Posology and method of administration

Adults and children over 5 years: Apply once or twice daily

##### 4.3 Contraindications

None

##### 4.4 Special warnings and precautions for use

Side effects include local hypersensitivity occasionally

##### 4.5 Interaction with other medicinal products and other forms of interaction

None known

##### 4.6 Pregnancy and lactation

May be used

##### 4.7 Effects on ability to drive and use machines

None

## 4.8 Undesirable effects

None known

## 4.9 Overdose

No cases known

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Starch is protective. Sulphur is mildly antiseptic and parasitocidal. Zinc Oxide is astringent and a soothing protective.

## 5.2 Pharmacokinetic properties

No information available

## 5.3 Preclinical safety data

No information available

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Tea Tree oil (Ti-Tree oil)  
Yellow Soft Paraffin

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf Life

3 years

## 6.4 Special precautions for storage

Do not store above 25°C

## 6.5 Nature and contents of container

Type I amber glass jar with hard plastic screwcap: 30 g.

## 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**

Potter's Ltd.  
1 Botanic Court  
Martland Park  
Wigan  
WN5 0JZ  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 471/11/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation:	30 <sup>th</sup> November 1992
Date of last renewal:	30 <sup>th</sup> November 2002

## **10 DATE OF REVISION OF THE TEXT**

December 2006