Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calamine Lotion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine Lotion BP contains Calamine 15% w/v and Zinc Oxide 5% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous suspension
Pale pink cutaneous suspension, with phenolic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Calamine has a mild astringent action on the skin. It is used as an astringent, antiperspirant, styptic, corrosive and mild antiseptic.
Calamine Lotion also allays the pain and swelling of pruritus, sunburn, dermatitis, skin irritations and rashes.

4.2 Posology and method of administration

Calamine Lotion is for external use only.

4.3 Contraindications

Hypersensitivity to any of the ingredients.
Poison: Not to be taken orally.

4.4 Special warnings and precautions for use

Keep all medicines away from children.

Avoid application prior to x-ray (zinc oxide may affect the outcome of the x-ray).

4.5 Interaction with other medicinal products and other forms of interaction

Zinc oxide may mask x-ray pictures under certain circumstances.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side-effects with Calamine Lotion are very rare.

Immune system disorders:
Frequency not known: Hypersensitivity reactions
If patients experience irritation, rash or itching which persists or becomes intolerable they should discontinue use immediately.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms of overdose: Overdose is considered unlikely with this product. If large quantities have been ingested, inflammation of the mucous membranes of the mouth and stomach, nausea, vomiting, diarrhoea, epigastric discomfort, weakness, mental confusion, cold sweats, depression of pulse and leg cramps may occur.

Treatment of overdose: The patient should be kept warm and pulmonary oedema, systemic acidosis, respiratory failure and circulatory failure should be treated systematically. Respiration may have to be assisted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calamine has a mild astringent action on the skin. Zinc salts are used as astringents, antiperspirants, styptics, corrosive and mild antiseptics. Their action may be due to the ability of Zinc to precipitate protein.
Calamine Lotion cools the skin by evaporation.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bentonite
Sodium Citrate
Phenol
Glycerol
Purified Water

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

Amber glass or high density polyethylene bottle of 70ml, 100ml, 140ml, 200ml and 500mg.

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

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd.
Ballymacarbry
Clonmel
Co. Tipperary
Trading as : Pinewood Healthcare

8 MARKETING AUTHORISATION NUMBER

PA0281/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 April 1999

Date of last renewal: 16 April 2009

10 DATE OF REVISION OF THE TEXT

September 2014