

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calamine Lotion BP 15% w/v Cutaneous Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine 15% w/v

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Suspension

A pale pink liquid with a faint smell of phenol.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Calamine Lotion is indicated for the symptomatic relief of skin irritation due to sunburn, heat rash and allergic reactions.

4.2 Posology and method of administration

Route of Administration: cutaneous use

Recommended Dosage Schedule:

Apply to the affected areas 3-4 times daily or as directed by the physician.

4.3 Contraindications

There are no contra-indications to the use of Calamine Lotion.

4.4 Special warnings and special precautions for use

If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is no known contra-indication to the use of Calamine Lotion during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Zinc Oxide
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

Calamine Lotion is filled into 500ml and 200ml polypropylene bottles that are fitted with polypropylene circular unwadded caps.

Not all pack sizes may be marketed.

6.6 Instructions for use and handling

Do not swallow, for cutaneous use only.

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Ltd

Bantry

Co. Cork

8 MARKETING AUTHORISATION NUMBER

PA 74/47/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th December 1994

Date of last renewal: 12th December 2004

10 DATE OF REVISION OF THE TEXT

May 2005