

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF MEDICINAL PRODUCT

NINO Calamine Lotion

2. GENERIC NAME

Calamine Lotion

3. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine Powder 15% w/v – 15g

Zinc Oxide 5% w/v – 5g

Bentonite – 3g

Sodium Citrate – 0.5g

Liquid Phenol 0.5% w/v - 0.5ml

Glycerine – 5ml

Propyl Hydroxybenzoate – 0.15g

Methyl Hydroxybenzoate – 0.5g

Deionized Water q.s. 100ml

4. PHARMACEUTICAL FORM

Lotion

5. CLINICAL PARTICULARS

I. Therapeutic indications

For relief of the symptoms of measles and dermatitis, reducing itching and discomfort

II. Posology and method of administration

Topical Application. Apply directly to the skin.

III. Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients

IV. Special warnings and precautions for use

Shake the bottle before use.

For external use only.

Keep all medicines out of the reach of children.

If symptoms persist after one week of administration consult your physician

V. Interaction with other medicinal products and other forms of interaction

May mask x-ray pictures under certain circumstances.

VI. Pregnancy and Lactation

No evidence is available as to the safety of the product when used during pregnancy and lactation therefore use with caution.

VII. Effects on the ability to drive and use machines

None Known

VIII. Undesirable effects

Occasional hypersensitivity or irritant reactions.

IX. Overdose

Overdose is considered unlikely with this product. However, if large quantities have been ingested, vomiting, inflammation of mucous membranes of the mouth and stomach, weakness, mental confusion, cold sweats, depression of pulse and leg cramps may occur.

Where phenol has been swallowed it may be necessary to empty the stomach by aspiration and lavage. Castor oil or olive oil may be added to the water to dissolve the phenol and delay absorption: 50 ml of oil may be left in the stomach.

The patient should be kept warm, and pulmonary oedema, systemic acidosis, respiratory failure and circulatory failure should be treated symptomatically. Respiration may have to be assisted.

6. PHARMACOLOGICAL PROPERTIES

I. Pharmacodynamics properties

Calamine has a mild astringent action of the skin and is used as a dusting powder, cream, lotion or ointment in a variety of skin conditions.

Zinc oxide has a mildly antiseptic action and is a mild astringent, it has soothing and protective properties.

II. Pharmacokinetic properties

Not applicable. It is for external use.

III. Preclinical safety data

None Known

7. PHARMACEUTICAL PARTICULARS

I. List of excipients

Bentonite
Sodium Citrate
Glycerine
Propyl Hydroxybenzoate
Methyl Hydroxybenzoate
Deionized Water

II. Incompatibilities

None

III. Shelf life

36 Months

IV. Special precautions for storage

Store below 30 °C in a cool dry place

V. Nature and contents of the container

100ml Amber PET bottle with 28mm cap
2 litre Amber HDP Plastic with inner plug and tamper-proof cover.

VI. Special precautions for disposal

None

8. <APPLICANT/MANUFACTURER>

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