

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calamine Lotion B.P.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine BP	15.0% w/v
Zinc Oxide BP	5.0% w/v
Liquefied Phenol BP	0.5% w/v
Glycerol BP	5.0% w/v

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lotion.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of minor skin rashes and irritation.

4.2 Posology and method of administration

For topical application. Applied directly to the skin.

Adults, older people and children

Apply to the affected area as required

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Shake the bottle before use.

For external use only.

Keep all medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions are known

May mask x-ray pictures under certain circumstances.

4.6 Fertility, pregnancy and lactation

The safety of Calamine Lotion during pregnancy and lactation has not been established. No significant problems have been reported, but use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Occasional hypersensitivity or irritation reactions.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdosage with calamine is very unlikely, if ingested symptoms of overdosage include anorexia, nausea, vomiting, epigastric discomfort and diarrhoea. Treatment consists of symptomatic measures only.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Calamine has astringent, antipruritic and mild antiseptic activity.

Zinc oxide is mildly astringent and forms a soothing and protective application.

Phenol is an antiseptic and disinfectant.

Glycerol is an osmotic agent with lubricating and moisturising properties.

5.2 Pharmacokinetic Properties

There is no evidence that calamine is absorbed through the skin.

No information is available on the absorption of zinc oxide through the skin. Zinc and its salts are poorly absorbed from the gastrointestinal tract. Zinc is widely distributed throughout the body and is excreted in the faeces with only traces in the urine.

Phenol is absorbed through the skin. It is metabolised to phenylglucuronide and phenyl sulphate and small amounts are oxidised to catechol and quinol which are mainly conjugated. The metabolites are excreted in the urine and on oxidation to quinones they may tint the urine green.

No information is available on the absorption of glycerol through the skin. Glycerol, taken orally, is readily absorbed from the gastrointestinal tract. It is extensively metabolised in the liver. It may be used in the synthesis of lipids, metabolised to glucose or glycogen, or oxidised to carbon dioxide and water. It may also be excreted unchanged in the urine.

5.3 Pre-clinical Safety Data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Bentonite B.P.
Sodium Citrate B.P.
Water (Potable) HSE

6.2 Incompatibilities

None stated

6.3 Shelf-Life

36 months.

6.4 Special Precautions for Storage

Store below 25°C.

6.5 Nature and Contents of Container

200 ml amber glass bottle with a white 'J' cap closure.

100 ml amber glass bottle with a white 'J' cap closure.

2 litre white polythene bottle with a white plastic screw cap with an EPE liner faced with aluminium.

500 ml white polythene bottle with a white plastic screw cap with an EPE liner faced with aluminium.

6.6 Special precautions for disposal

No special instructions.

7. MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Limited
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8. MARKETING AUTHORISATION NUMBER

PL 18374/0033

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/04/2005

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27/05/2015