

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calamine and Glycerin Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredients</u>	<u>% w/w</u>
Zinc Oxide Ph Eur	5
Calamine BP	15
Glycerin Ph Eur	5

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of sunburn, windburn, rough, dry hands, chapped and tender skin and for the relief of skin irritation.

4.2 Posology and method of administration

For topical application

Adults and Children:

To be applied gently to the affected parts when required.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

For external use only.

Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

May mask x-ray pictures under certain circumstances.

4.6 Fertility, Pregnancy and lactation

The safety of Calamine and Glycerin Cream during pregnancy and lactation has not been established but its use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Occasional hypersensitivity 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 or search Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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 a mild astringent action on the skin. Zinc oxide has mild astringent, soothing and protective qualities.

Glycerol has emollient properties.

5.2 Pharmacokinetic properties

Not available.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polawax A31
Paraffin light liquid
Isopropyl myristate
Polysorbate 80
Bentonite
Sodium citrate gran
Water purified
Liquefied phenol

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

An internally lacquered collapsible tube with latex welt having a polypropylene or polythene cap, in a cardboard carton.

Pack size: 35 gm.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Crest Medical Limited
Unit 5 Farrell Industrial Estate
Howley Lane Warrington
WA1 2PB
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 01021/0207

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 9 November 1984
Last Renewal: 22 December 1994

10 DATE OF REVISION OF THE TEXT

09/07/2025