

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aqueous Calamine Cream BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine 4.0% w/w and Zinc Oxide 3.0% w/w

Excipient(s) with specified warnings

Cetostearyl alcohol 4.0% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of the symptoms of mild sunburn and other minor skin conditions.

4.2 Posology and method of administration

Topical application.

Adults, elderly and children: apply liberally to dry, clean skin as required.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For external use only.

Keep securely closed when not in use.

Keep out of the sight and reach of children.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Ingredients with specified warnings

This medicine contains Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

May mask x-ray pictures under certain circumstances.

4.6 Fertility, pregnancy and lactation

No information is available on the use of this product during pregnancy and lactation. However, it is unlikely that its use would cause any adverse effects.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Occasional hypersensitivity or irritant 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 for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Both Zinc Oxide and Calamine exhibit a mild astringent action when applied to the skin.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin, glyceryl monostearate, macrogol cetostearyl ether 22, cetostearyl alcohol, phenoxyethanol, purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months unopened
Use within 12 months of first opening

6.4 Special precautions for storage

Do not store above 25°C.
Do not allow to freeze.

6.5 Nature and contents of container

100g: White polyethylene/Aluminium/co-polymer MDPE laminated plastic tube, with polypropylene cap.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.
Linthwaite Laboratories
Huddersfield
HD7 5QH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/6276R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/06/1988 / 15/06/2001

10 DATE OF REVISION OF THE TEXT

04/09/2019