

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oily Calamine Lotion BP 1980

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Arachis Oil BP 45.6% w/v

Calamine BP 5.0% w/v

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lotion

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of minor skin irritation and pruritus.

4.2 Posology and method of administration

Adults the elderly and children

The product should be applied to the skin. Repeat as required.

Shake the bottle well before applying the product.

Method of administration

For topical application

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Oily Calamine Lotion B.P. 1980 contains arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid Oily Calamine Lotion B.P. 1980.

The product is for external use only. Keep out of the reach of children.

4.5 Interaction with other Medicinal Products and other Forms of Interaction

None known.

4.6 Fertility, pregnancy and lactation

No significant problems have been reported.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

None known. However, the product is preserved with phenonip, which contains a mixture of the esters of 4-hydroxybenzoic acid and phenoxyethanol: some patients may be hypersensitive to the preservative or other constituents of the product.

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

As the product is for topical use, the likelihood of overdosage due to ingestion is small; should it occur then treatment includes induction of emesis followed by supportive therapy accompanied by gastric lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Arachis oil is used topically as an emollient to soothe inflamed skin. Calamine has a mild astringent action on the skin.

5.2 Pharmacokinetic Properties

Arachis oil

Apart from the fact that it is absorbed through the skin to act as an emollient when applied topically, little is given in the literature concerning the Pharmacokinetic of arachis oil via this route of administration.

Calamine

Apart from the fact that it is a mild astringent when applied topically little is given in the literature concerning the pharmacokinetics of calamine via this route of administration.

5.3 Preclinical Safety Data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Phenonip
Wool fat
Oleic acid
Calcium hydroxide solution

6.2 Incompatibilities

No significant incompatibilities have been reported..

6.3 Shelf Life

36 months.

6.4 Special Precautions for Storage

Store below 25°C.

6.5 Nature and Contents of Container

Dispensing pack

500 ml amber glass bottle, plastic screw cap with an aluminium foil lined expanded polyethylene liner.

2 litre amber glass bottle, plastic screw cap with an aluminium foil lined expanded polyethylene liner.

Patient packs or OTC packs as appropriate

500 ml amber glass bottle, plastic screw cap with an aluminium foil lined expanded polyethylene liner.

200 ml amber glass bottle with a white Jay cap closure.

6.6 Special precautions for disposal

None stated

7. MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Ltd
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8. MARKETING AUTHORISATION NUMBER

PL 18374/0034

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14th May 1986 / 14th April 1994

10 DATE OF REVISION OF THE TEXT

23/12/2015