

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Caldease 15% w/w Medicated Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc oxide 15% w/w.

Excipients with known effect

Methylhydroxybenzoate 0.40 % w/w, Propylhydroxybenzoate 0.10 % w/w, Lanolin oil 5.00 % w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

A grey-white ointment with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Caldease Ointment promotes the healing of nappy rash. Protects irritated skin and smoothes minor skin irritations, superficial wounds and burns.

4.2 Posology and method of administration

Posology

Apply each time after area has been cleansed and dried.

Nappy rash

To help prevent nappy rash, apply a smooth even coating of ointment at each nappy change.

There is no recommended dose schedule.

Method of administration

For topical administration only.

4.3 Contraindications

1. Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
2. Use in the treatment of fungal infections.
3. Use on large surface wounds and major burns.

4.4 Special warnings and precautions for use

If there is no improvement, or there is aggravation of the condition, consult the doctor.

Contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

Contains lanolin oil which may cause local skin reactions (e.g., contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation

None.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

None.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc Oxide has mild astringent and protective properties. Caldease Ointment protects irritated skin and soothes minor skin irritations, superficial wounds and burns.

It is applied topically to promote healing of nappy rash.

It protects and soothes irritated skin by forming a moisture barrier against wetness.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc
Cod liver oil
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
White soft paraffin
Lanolin oil
Fragrance intrarome 16797

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube lined with epoxy/phenolic resin lacquer and fitted with a white polythene cap.

Pack sizes:30 g and 100 g

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/153/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 January 1985

Date of last renewal: 01 April 2009

10 DATE OF REVISION OF THE TEXT

November 2019