

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Caldesene Adult 10% w/w Medicated Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Undecylenate 10% w/w.

Excipient(s) with known effect

Contains benzyl benzoate, benzyl alcohol, eugenol, isoeugenol, linalool, cinnamyl alcohol and coumarin.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Powder.

A white, perfumed, free flowing cutaneous powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Protects against skin irritation and chaffing especially in delicate skin folds.

4.2 Posology and method of administration

Adults: Apply to affected area as required or as directed by a physician.

There is no recommended dosing schedule.

Method of administration:

Topical.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

This medicine contains fragrance with: benzyl alcohol, benzyl benzoate, eugenol , isoeugenol, linalool, cinnamyl alcohol and coumarin. which may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

As this product is applied topically, its use is not contra-indicated during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

None known.

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 HPRC 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

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Undecylenic Acid, combinations
ATC Code: D01AE 54

Calcium Undecylenate has antibacterial and antifungal properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No additional information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc

Fragrance*

* Contains benzylalcohol, benzyl benzoate, eugenol, isoeugenol, linalool, phenethyl alcohol, cinnamyl alcohol and coumarin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed.

6.5 Nature and contents of container

Polypropylene container with polypropylene sprinkler lid.

Pack size: 20, 55, 100 or 150 g

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or wastematerial should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/247/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th March 2014

Date of last renewal: 13th March 2019

10 DATE OF REVISION OF THE TEXT

May 2020