

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Caldesene 10% w/w Medicated Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Undecylenate 10 % w/w

Excipients with known effect

Benzyl benzoate <0.25% w/w.

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

For the prevention and treatment of local rashes of buttocks due to friction and irritation particularly those at risk of infection such as nappy rash.

4.2 Posology and method of administration

Nappy rash: Cleanse and dry the affected area, sprinkle on Caldesene after each nappy change or as directed by a doctor.

Prevention: Apply to affected area as required or as directed by a doctor.

Treatment: Cleanse and dry the affected area, apply powder as required or as directed by a doctor.

There is no recommended dosing schedule.

Method of administration:

For Cutaneous use.

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 product contains benzyl benzoate which may be a mild irritant to the skin, eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interactions

Not applicable.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Skin irritation can occur occasionally to some of the ingredients. If this occurs, use of the product should be discontinued.

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
Perfume Undeca 4875*

* contains benzyl benzoate, eugenol, isoeugenol and phenyl ethyl alcohol white.

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 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

PA0126/152/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 April 1977

Date of last renewal: 03 April 2008

10 DATE OF REVISION OF THE TEXT

May 2019