Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calmurid 10%/ 5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cream contains 100 mg of Urea (10% w/w) and 50 mg of Lactic acid (5% w/w).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A homogenous, white, oil-in-water cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of dermatoses characterised by hyperkeratosis.

4.2 Posology and method of administration

For external use only.

Adults, paediatric population and older people

Application: twice daily or as directed by the physician, ideally after washing.

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

Calmurid is acidic and hypertonic and can cause smarting if applied to raw areas, fissures or mucous membranes. Where this is a barrier to therapy the use of Calmurid diluted 50% with aqueous cream B.P. for one week should result in freedom from smarting upon use of Calmurid.

Avoid contact with the eyes and surrounding area and do not apply Calmurid on inflamed skin or open wounds.

Because of potential transcutaneous penetration of urea, the product should not be used extensively in subjects with severe renal impairment without medical supervision.

4.5 Interaction with other medicinal products and other forms of interactions

Low pH of the cream might affect stability of other drugs.

Urea may enhance the penetration of other active substances into the skin. This is particularly well-known for corticosteroids, dithranol and 5-fluoruracil.

4.6 Fertility, pregnancy and lactation

There is no specific data available regarding the use in pregnant women and during lactation.

In breast-feeding women Calmurid should be removed from the breast area before breast feeding.

4.7 Effects on ability to drive and use machines

Calmurid has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Calmurid is acidic and hypertonic and can cause smarting if applied to raw areas, tissues or mucous membranes. If smarting occurs, wash the cream off.

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

Unlikely as the product is a topical preparation. In the case of overuse, wash the cream off.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Carbomide products

ATC code: D02AE

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl Monostearate
Betaine Monohydrate
Diethanolamine Cetylphosphate
Hard Fat
Cholesterol
Sodium Chloride
Purified Water

6.2 Incompatibilities

Low pH due to lactic acid should be considered if repackaging or admixing other drugs.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Tubes
White low density polyethylene tubes fitted with white polypropylene screw caps. Package sizes: 15,20,30,50,100g.
Pump dispenser: White polypropylene bottle fitted with a white polyethylene closure and a natural polyethylene follower plate. Package sizes: 400,500g
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Galderma International S.A.S.
Tour Europlaza
La Défense 4
20 Avenue André Prothin
France

8 MARKETING AUTHORISATION NUMBER

PA22743/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th July 1978
Date of last renewal: 16th November 2008

10 DATE OF REVISION OF THE TEXT

May 2019