Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calmurid HC 10%/5%/1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urea	10.0 % w/w
Lactic acid	5.0 % w/w
Hydrocortisone	1.0 % w/w

For the full list of excipients,
see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A smooth white, oil-in-water cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of dermatoses characterised by hyperkeratosis and inflammation.

4.2 Posology and method of administration

For external use only.

Apply twice daily to the affected areas or as directed by the physician.

4.3 Contraindications

1. Use in the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.

2. Use in acne rosacea or in perioral dermatoses.

3. Use in plaque psoriasis.

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

4.4 Special warnings and precautions for use

1. Continuous treatment longer than three weeks should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression and growth retardation.

2. Prolonged use of uninterrupted occlusion (including napkins) or use with extensive occlusive dressings may suppress adrenocortical function.

3. Continuous application without interruption will result in local atrophy of the skin, striae, and superficial vascular dilation, particularly on the face.

4. Prolonged use in the management of acne vulgaris should be avoided.

5. Use in psoriasis may lead to generalisation, excessive systemic absorption and rebound relapse on cessation of use.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

Animal studies have shown teratogenic effects. To date similar effects have not been shown to occur in man. This product should not be used in pregnancy or lactation unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

If applied to open wounds or mucous membranes the hypertonic and acidic nature of the preparation may produce smarting. In such cases wash off with water. Where smarting is a barrier to therapy, dilute with an equal quantity of aqueous cream: after a week of treatment with this material, the normal strength should be tolerated.

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:
Ireland
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

The barrier function in the skin to steroid uptake, the low toxicity of hydrocortisone and the natural mechanism for its rapid inactivation make overdose unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A combination of a synthetic form of a naturally occurring corticosteriod, absorbable in part after topical application, with a keratolytic.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Urea, lactic acid and hydrocortisone are long established materials whose pre-clinical profile is known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl monostearate
Betaine monohydrate
Diethanolamine cetylphosphate
Hard fat
Cholesterol
Sodium chloride
Purified water

6.2 Incompatibilities

Do not mix with other preparations, as the effect on the stability of each is unknown. Do not pack in alloy containers as they may react with the lactic acid.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene tubes.

Pack sizes: 30g, 50g & 100 g.
Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA22743/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1978
Date of last renewal: 20th April 2009

10 DATE OF REVISION OF THE TEXT

May 2019