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 for topical (cutaneous) use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To be used topically for the treatment of atopic eczema, Besniers prurigo, acute and chronic allergic eczema, neurodermatitis and other hyperkeratotic skin conditions with accompanying inflammation.

4.2 Posology and method of administration

For external use only.

Adults, paediatric population and older people:

Apply twice daily to the affected area after bathing or washing. Moist lesions should be treated as to dry them before using Calmurid HC.

4.3 Contraindications

Skin tuberculosis, viral infections accompanied by dermal manifestations e.g. herpes simplex, vaccinia, chicken pox and measles. Syphilitic skin lesions. In
concurrent mycotic infections, the cream should be complemented with antimycotic treatment. Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In infants, high surface area in relation to mass raises the likelihood of uptake of excessive amounts of steroid from the cream, even without occlusion, thus adrenal suppression is more likely. In infants, long term continuous topical therapy should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

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

Pregnancy
Evidence from animal studies suggests that prolonged intensive therapy with steroids during pregnancy should be avoided.

Breast-feeding
Given the slow uptake of hydrocortisone from the skin and the rapid destruction of hydrocortisone by the body, there would seem to be little risk of significant transfer at lactation.

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 the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard
4.9. **Overdose**

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

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**

Pharmacotherapeutic group: Corticosteroids, weak, other combinations

ATC code: D07XA

Urea at a concentration of 10% has keratolytic, anti microbial, anti pruritic and hydrating effects on the skin, properties also attributable to Lactic acid. Hydrocortisone 1% is the normal concentration of the drug used as a dermatological anti-inflammatory agent. In some patients with eczema, Calmurid HC cream may be as effective as fluorinated steroid creams.

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 ("Amphisol")
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.
Package sizes: 15, 30, 50g 100 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PL 10590/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd February 2006
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06/11/2013