

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Locoid Crelo Topical Emulsion 0.1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The emulsion contains Hydrocortisone butyrate 0.1% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Topical emulsion

White to almost white, opaque, viscous, oil-in-water emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The product is recommended for clinical use in the treatment of conditions responsive to topical corticosteroids, e.g. eczema, dermatitis and psoriasis. The product is intended for topical application especially to the scalp or hirsute skin.

Topical corticosteroids are not generally indicated in psoriasis but may be acceptable in psoriasis excluding widespread plaque psoriasis provided warnings are given, see section 4.4 Special Warning and special precautions for use.

4.2 Posology and method of administration

For topical application.

Dosage: to be applied evenly and sparingly two or three times daily.

Adults and the elderly: the same dose is used for adults and the elderly, as clinical evidence would indicate that no special dosage regimen is necessary in the elderly.

Children and infants: long term treatment should be avoided. Courses should be limited to seven days where possible.

The formulation of the product makes it suitable for use in both scaly lesions and for moist, weeping lesions.

4.3 Contraindications

Hypersensitivity to hydrocortisone or to any of the ingredients of the lotion.

This preparation is contraindicated in the presence of untreated viral or fungal infections, tubercular or syphilitic lesions, peri-oral dermatitis, acne vulgaris and rosacea and in bacterial infections unless used in connection with appropriate chemotherapy.

4.4 Special warnings and precautions for use

Although generally regarded as safe, even for long-term administration in adults, there is a potential for adverse effects if over used in infancy. Extreme caution is required in dermatoses of infancy including napkin eruption. In such

patients courses of treatment should not normally exceed 7 days.

As with all corticosteroids, application to the face, flexures and other areas of thin skin may cause skin atrophy and increase absorption and should be avoided.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapse following development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin. Steroids may have a place in psoriasis of the scalp and chronic plaque psoriasis of the hands and feet. Careful patient supervision is important.

Keep away from the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

Theoretically, there is the possibility that if maternal systemic absorption occurred the infant's adrenal function could be affected.

The safety of topical corticosteroids during lactation has not been established. The potential benefit of topical corticosteroids, if used during lactation, should be weighed against possible hazard to the nursing infant.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Local atrophic changes may occur, particularly in skin folds, intertriginous areas or in nappy areas in young children where moist conditions favour hydrocortisone absorption. Systemic absorption from such sites may be sufficient to produce hypercorticism and suppression of the pituitary adrenal axis after prolonged treatment. This effect is more likely to occur in infants and children and if occlusive dressings are used or large areas of skin treated. Napkins may act as occlusive dressings.

4.9 Overdose

Excessive use, especially under occlusive dressings or over a long period of time, may produce adrenal suppression. No special procedures or antidote. Treat any adverse effects symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active constituent, hydrocortisone butyrate, is an established topical corticosteroid, equi-efficacious with those corticosteroids classified as potent.

5.2 Pharmacokinetic properties

In human in-vivo studies, the potency of this form of active ingredient has been shown to be of the same order as other

topical corticosteroids classed as potent. The active ingredient metabolises to hydrocortisone and butyric acid.

5.3 Preclinical safety data

The well-established use of hydrocortisone butyrate topical preparations over many years does not warrant further safety evaluation studies in animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl Alcohol
White soft paraffin
Hard paraffin
Borage oil
Butylhydroxytoluene
Propylene glycol
Sodium citrate
Anhydrous citric acid
Propyl parahydroxybenzoate
Butyl hydroxybenzoate
Purified water

6.2 Incompatibilities

None stated.

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

White opaque low density polyethylene bottles of 15, 25, 30, 50 and 100g capacity, equipped with a natural low density polyethylene dropper applicator, closed with a white polypropylene screw cap.

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

Astellas Pharma Europe Ltd
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2353EW Leiderdorp
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8 MARKETING AUTHORISATION NUMBER

PA 1244/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 4 April 2002

10 DATE OF REVISION OF THE TEXT

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