Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mildison Lipocream 1.0 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains Hydrocortisone 1.0 %w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
White or practically white smooth cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Eczema and dermatitis of all types including atopic eczema, otitis externa, primary irritant and allergic dermatitis, intertrigo, prurigo nodularis, seborrhoeic dermatitis, and insect bite reactions.

4.2 Posology and method of administration

For topical application.

For adults, children and the elderly:
Apply a small quantity only sufficient to cover the affected area two or three times a day. Due to the formulation of the base the product may be used both for dry scaly lesions and for moist or weeping lesions.

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

4.3 Contraindications

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

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 overdosage in infancy. Extreme caution is required in dermatoses of infancy including napkin eruption. In such patients courses of treatment should not normally exceed seven 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.

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 substance is a well-established topical corticosteroid, with an activity classified as mild.

5.2 Pharmacokinetic properties

In-vivo studies have demonstrated the topical activity of the product, e.g. by the McKenzie-Stoughton test.

5.3 Preclinical safety data

No relevant pre-clinical safety data has been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Macrogol cetostearyl ether
Light liquid paraffin

White soft paraffin
Methyl parahydroxybenzoate
Sodium citrate anhydrous
Citric acid anhydrous
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Collapsible membrane-necked internally coated aluminium tubes with a polyethylene screw cap containing 10g, 15g, 30g or 100 g.

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
Elisabethhof 19
2353EW Leiderdorp
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA 1244/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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