Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lotriderm 0.064% w/w + 1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone dipropionate	0.064	% w/w
Clotrimazole	1.0	% w/w

Excipients: Propylene glycol 10% w/w
Cetostearyl alcohol 7.2% w/w
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
Smooth, uniform, white to off-white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the topical management of corticosteroid responsive dermatoses, with actual or potential secondary fungal infection.

4.2 Posology and method of administration

Adults and children over the age of 12 years :

Topical administration. Application to the affected area usually one to three times daily or as directed by the physician.

4.3 Contraindications

Lotriderm is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids or imidazoles.

If irritation or sensitisation develops with the use of Lotriderm cream, treatment should be discontinued and appropriate therapy instituted.

Lotriderm cream is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections.

4.4 Special warnings and precautions for use

Lotriderm Cream should not be used with occlusive dressings.

If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided, particularly in infants and children where adrenal suppression may occur even without occlusion.

If irritation or sensitisation develop, treatment should be discontinued and appropriate remedial therapy instituted.

In the presence of bacterial or viral infection, an appropriate antibacterial or antiviral agent should be administered concurrently. If response does not occur promptly, Lotriderm should be discontinued until the infection has been controlled adequately.
Systemic absorption of topical corticosteroids will be increased if extensive body surface areas or skin folds are treated. Suitable precautions should be taken under these conditions or when long term use is anticipated, particularly in infants and children.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, espeically in infants and children.

Hypothalamic-pituitary adrenal axis suppression. Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

The safety and effectiveness of Lotriderm in children below the age of 12 has not been established.

Lotriderm Cream is not intended for ophthalmic use.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Fertility, pregnancy and lactation

Studies in animals have shown a teratogenic effect. To date no such effects have been reported in human beings during pregnancy or lactation. However, this product should not be used in pregnancy or lactation unless considered essential by the physician.

It is not known whether the components of Lotriderm are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse reactions reported for Lotriderm include : burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritis, urticaria and general irritation of the skin.

Reactions to betamethasone dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria, capillary fragility (ecchymoses) and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported. (See section 4.4)

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: http://www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Acute overdosage with topical application of Lotriderm cream is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of Lotriderm cream. Accidental ingestion should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lotriderm Cream contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent.

Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory anti-pruritic and vasoconstrictive actions.

Clotrimazole is an agent with activity against fungal skin infections.

5.2 Pharmacokinetic properties

Lotriderm Cream is intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action. Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
White soft paraffin
Cetostearyl alcohol
Macrogol cetostearyl ether
Benzyl alcohol
Sodium dihydrogen phosphate dihydrate
Concentrated phosphoric acid
Sodium hydroxide (for pH-adjustment)
Propylene glycol (E1520)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Epoxy-lined aluminium tubes with low density polyethylene caps. Tubes contain 15 g, 30 g or 50 g.

Not all pack sizes may be marketed.

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

Merck Sharp & Dohme Ireland (Human Health) Limited
Red Oak North
South County Business Park
Leopardstown
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1286/31/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 July 1987

Date of last renewal: 24 July 2007

10 DATE OF REVISION OF THE TEXT

February 2016