SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

LOTRIDERM 0.05% w/w/1.0% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone dipropionate 0.064% w/w*
(* equivalent to 0.05% betamethasone)
Clotrimazole 1.0% w/w

Excipients with known effect
Cetostearyl alcohol,
Propylene glycol, 100mg/g of cream
Benzyl alcohol, 10mg/g of cream
For the 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

Short-term topical treatment of tinea infections due to Trichophyton rubrum; T. mentagrophytes; Epidermophyton floccusum and Microsporum canis; candidiasis due to Candida albicans.

4.2 Posology and method of administration

Posology
Adults and children over the age of 12 years. Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidiasis) or for four weeks (tinea pedis).

Paediatric population
Lotriderm cream is not recommended for children under the age of twelve years.

Method of administration
Topical administration only.

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

4.4 Special warnings and precautions for use

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

LOTRIDERM CREAM SHOULD NOT BE USED WITH OCCLUSIVE DRESSING.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

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, especially in infants and children.

Lotriderm Cream is not intended for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population

- Long term continuous therapy should be avoided in all children irrespective of age.
- Lotriderm cream should not be used with adhesive dressing.

- The safety and effectiveness of Lotriderm cream has not been established in children below the age of 12.
- If used on children, courses should be limited to 5 days.

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.

Lotriderm cream contains:

Cetostearyl alcohol which may cause localised skin reactions (e.g. contact dermatitis).

Propylene glycol which may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns).

Benzyl alcohol which may cause allergic reactions or mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

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 human foetus. Hence Lotriderm Cream should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Breast-feeding
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

Lotriderm cream has no influence on the ability to drive and use machines.

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, pruritus, 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), blurred vision and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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. Signs of toxicology appearing after such 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 a broad-spectrum antifungal agent with activity against Trichomones, Staphylococci and Bacteroides.

5.2 Pharmacokinetic properties

Lotriderm 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
Phosphoric acid concentrated
Sodium hydroxide
Propylene glycol (E 1520)
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

The product will be marketed in standard epoxy-lined aluminium tubes with low density polyethylene caps. Tubes will contain 2g or 5g (Professional Sample Packs), 15g, 30g or 50g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Organon Pharma (UK) Limited
Shotton Lane
Cramlington
United Kingdom
NE23 3JU

8 MARKETING AUTHORISATION NUMBER(S)

PL 00025/0568

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/07/2007

10 DATE OF REVISION OF THE TEXT

29/11/2024