

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

CLARELUX 500 micrograms/g cutaneous foam in pressurised container.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cutaneous foam contains 500 micrograms clobetasol propionate.

Excipients with known effect:

cetyl alcohol 11.5 mg/g, stearyl alcohol 5.2 mg/g and propylene glycol 20.9 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous foam in pressurised container.

White foam that breaks down upon contact with skin.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Short-course treatment of steroid responsive dermatoses of the scalp such as psoriasis, which do not respond satisfactorily to less active steroids.

4.2 Posology and method of administration

Posology

Use in adults

CLARELUX is a highly potent topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks and amounts greater than 50 g/week should not be used.

Route of administration: for cutaneous use.

CLARELUX should be applied to the affected area twice daily. There are no data from clinical studies evaluating the efficacy of once daily application.

Paediatric population

As there are no data regarding the use of CLARELUX in children and adolescents, use in these patients is not recommended.

Method of administration

The foam application has been designed so that the preparation spreads easily without being too fluid and allows easy application direct to the affected area.

Note: for proper dispensing of foam, hold the container upside down and depress the actuator.

Invert the container and dispense a small amount (of the size of a walnut or one teaspoon) of CLARELUX directly on the lesions, or dispense a small amount into the cap of the container, onto a saucer or other cool surface, taking care to avoid contact with eyes, nose, and mouth. Dispensing directly onto hands is not recommended, as the foam will begin to melt immediately upon contact with warm skin. Gently massage into affected area until the foam disappears and is absorbed. Repeat until entire affected area is treated. Move the hair away from the affected area so that the foam can be applied to each affected area.

Avoid contact with eyes, nose and mouth.

Do not use near a naked flame.

4.3 Contraindications

CLARELUX is contraindicated in patients with:

- hypersensitivity to clobetasol propionate, to other corticosteroids, or to any of the excipients listed in section 6.1;
- ulcerated lesions, burns;
- rosacea;
- acne vulgaris;
- perioral dermatitis;
- perianal and genital pruritus.

The use of CLARELUX is contraindicated in the treatment of primary infected skin lesions caused by infection with parasites, viruses, fungi or bacteria.

CLARELUX must not be used on the face.

CLARELUX must not be applied to the eyelids (risk of glaucoma and cataract).

4.4 Special warnings and precautions for use

Special warnings

Hypersensitivity

CLARELUX should be used with caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions (see section 4.8) may resemble symptoms of the condition under treatment.

Stop using immediately if signs of hypersensitivity appear.

Infections and infestations

The use of CLARELUX[®] on wounds or ulcerations is not recommended.

Secondary infection may develop; bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Adrenal suppression

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals, particularly in children as a result of increased systemic absorption of topical steroids.

If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see section 4.8).

Long-term continuous topical therapy should be avoided as adrenal suppression can occur readily even without use with an occlusive dressing. Upon clearing of lesions or after a maximum treatment period of two weeks, change to intermittent therapy or consider replacing with a weaker steroid.

Precautions for use

Increased systemic absorption of topical steroids

Increased systemic absorption of topical steroids can lead to occurrence of systemic adverse reactions (i.e., adrenal suppression, immunosuppression). Increased systemic absorption of topical steroids can be facilitated by:

- long term exposure,
- application to a large surface area,
- use on occluded skin areas (e.g. on intertriginous areas or under occlusive dressings),
- use on thin areas (e.g. face),
- use on broken skin or other conditions where the skin barrier may be impaired,

- and increasing hydration of the stratum corneum.

Unless supervised by a physician, CLARELUX should not be used with occlusive dressings.

Rebound phenomenon

A rebound phenomenon in the form of flushing, stinging and burning of the skin may be seen in the event of sudden discontinuation after long-term use. This can be avoided by withdrawing treatment gradually.

Topical corticosteroids may be hazardous because rebound relapses can follow development of tolerance. Patients may also be exposed to the risk of developing generalised pustular psoriasis and local or systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Eye disorders

Systemic corticosteroids therapy is associated with glaucoma and cataract formation. This risk has also been reported during ophthalmic treatment, and during regular local corticosteroid application to the eyelids. Additionally there have been reports of cataracts and glaucoma in patients following prolonged potent topical corticosteroid overuse on the face and/or the body. Although hypertensive effect of topical steroid is usually reversible after cessation of treatment, the visual defects resulting from glaucoma and cataracts are irreversible.

CLARELUX should not be applied on the eyelids.

Patients should wash their hands after each application to avoid eye contamination with CLARELUX. If CLARELUX becomes in contact with the eye, the affected eye should be bathed in copious amounts of water.

Patients on prolonged courses of potent topical steroids should be screened for cataract and glaucoma on a regular basis, especially patients with known risk factors for cataract (e.g. diabetes, smokers) or for glaucoma (e.g. personal or family history of glaucoma).

Excipients with known effect

This medicinal product contains propylene glycol, which may cause skin irritation. This medicinal product also contains cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed using CLARELUX.

4.6 Fertility, pregnancy and lactation

Pregnancy

Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development (see section 5.3). There are no adequate and well-controlled studies of clobetasol propionate in pregnant women. Epidemiological studies in pregnant women following use of oral corticosteroids have indicated little or no risk with regard to an association with cleft palate. Limited evidence suggests a small risk for low birth weight when using large amounts of potent/very potent topical corticosteroids such as clobetasol propionate in pregnancy.

CLARELUX in pressurised container should not be used during pregnancy unless clearly necessary.

Breast-feeding

The safe use of clobetasol propionate during lactation has not been established. Glucocorticosteroids are excreted in breast milk, therefore CLARELUX 500 micrograms/g, cutaneous foam in pressurised container should not be used in breast-feeding women unless clearly necessary.

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

Clobetasol administered subcutaneously to rats decreased fertility in females at the highest dose (see section 5.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Summary of the safety profile

As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas can result in adrenocortical suppression. This is likely to be transient if the weekly dosage does not exceed 50g in adults.

Prolonged and intensive treatment with a highly active corticosteroid preparation may cause local changes in the skin such as skin atrophy, ecchymoses secondary to skin atrophy, skin fragility, telangiectasia, especially on the face, striae particularly affecting the proximal limbs.

Additional local adverse events associated with glucocorticosteroids include perioral dermatitis, rosacea-like dermatitis, delayed wound healing, rebound phenomenon which can lead to dependence on corticosteroids, and effects on the eyes. Rise of intraocular pressure and increased risk for cataract are known side effects for glucocorticosteroids (see section 4.4).

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease (see section 4.4).

Secondary infection may develop; bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied. If the product is not used properly, bacterial, viral, parasitic, and fungal infections may be masked and/or aggravated (see section 4.4). Folliculitis has also been reported.

Contact allergy to CLARELUX or one of the excipients may occur. If signs of hypersensitivity appear, applications should be stopped immediately. Exacerbation of symptoms may occur.

The most commonly observed adverse reactions associated with the use of clobetasol propionate cutaneous foam formulations in clinical trials were application site reactions including burning (5%) and other non-specified reactions (2%).

Tabulated list of adverse reactions

The adverse reactions are classified by System Organ Class and frequency, using the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (<1/10,000), not known (cannot be estimated from the available data)".

SOC	Common	Very rare	Unknown
Infections and infestations			Secondary infections Folliculitis
Endocrine disorders		Pituitary adrenal system suppression	
Nervous system disorders		Paraesthesia	
Eye disorders		Eye irritation	Cataract
Skin and subcutaneous tissue disorders		Vasodilatation Dermatitis NOS Dermatitis contact Psoriasis aggravated Skin irritation Skin tenderness Skin tightness.	Pigmentation change Hypertrichosis
General disorders and administration site conditions	Application site burning Application	Application site erythema Application site	

	site reaction NOS	pruritus Pain NOS	
Investigations		Blood urine present Mean cell volume increased Protein urine present Urine nitrogen	

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 via

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

4.9 Overdose

No overdoses have been reported. Topically applied CLARELUX can be absorbed in sufficient amounts to produce systemic effects. If features of hypercorticism appear topical steroids should be discontinued gradually and, because of the risk of acute adrenal suppression, this should be done under medical supervision.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, very potent (group IV)
ATC code: D07A D01

Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The precise mechanism of the anti-inflammatory activity of topical steroids in the treatment of steroid-responsive dermatoses, in general, is uncertain. However, corticosteroids are thought to act by the induction of phospholipase A₂ inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A₂.

A vasoconstrictor study has shown that CLARELUX has a comparable potency, based upon skin blanching response, as other clobetasol propionate formulations.

5.2 Pharmacokinetic properties

Topical corticosteroids can be absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver, and are then excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

In a controlled pharmacokinetic study, 3 of 13 subjects experienced reversible suppression of the adrenals at any time during the 14 days of CLARELUX therapy to at least 20% of the body surface area.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity and genotoxicity. No topical studies were performed to assess the safety, pharmacology and the carcinogenic potential of clobetasol.

Parenteral administration of corticosteroids, including clobetasol propionate, to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. Animal studies have indicated that intrauterine exposure to corticosteroids may contribute to the development of cardiovascular and metabolic diseases in adult life, but there is a lack of evidence for the occurrence of such effects in humans (see section 4.6).

In fertility studies, subcutaneous administration of clobetasol propionate to rats at doses of 6.25 to 50 micrograms/kg/day produced no effects on male fertility. In females, increased embryofetal loss and growth suppression and thymic atrophy in the litters were observed at the highest dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol anhydrous
Purified water
Propylene glycol
Cetyl alcohol
Stearyl alcohol
Polysorbate 60
Citric acid anhydrous
Potassium citrate

Propellant: propane/*n*-butane/isobutane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate. Store upright.

The canister contains a pressurised, flammable liquid. Do not use near a naked flame. Do not expose to temperatures higher than 50°C or to direct sunlight. Do not pierce or burn the canister, even when empty.

6.5 Nature and contents of container

Pressurised aluminium container closed with an inverted valve, containing 50g or 100g of foam. The inside of the can is lined with a double coated, clear epoxy-phenolic lacquer. Each filled canister is fitted into a spout actuator with dust cap.

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

Pierre Fabre Dermatologie
45 Place Abel-Gance
92100 Boulogne Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA1230/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 March 2005
Date of last renewal: 20 June 2008

10 DATE OF REVISION OF THE TEXT

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