Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ClobaDerm 0.5mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of cream contains 0.5 mg of clobetasol propionate (0.05% w/w).

Excipients with known effect
Also contains 80 mg of cetostearyl alcohol, 475 mg of propylene glycol and 0.75 mg of chlorocresol in each gram of the cream.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

White or almost white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Short courses for the treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other skin conditions which do not respond satisfactorily to less active steroids.

4.2 Posology and method of administration

Posology

Adult and children
Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. The application frequency should be gradually reduced.

Repeated short courses of ClobaDerm may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of ClobaDerm can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

Rarely, occlusion is necessary. In cases where an occlusive dressing is applied, caution is needed in order to avoid the risk of local and systemic adverse events.

Clobaderm should only be used for no more than 5 days on the face and eyelids.

Method of administration

For topical administration.

Application of cream in adults:
- two fingertips of cream will cover both hands or one foot
- three fingertips of cream will cover one arm
- six fingertips of cream will cover one leg
- fourteen fingertips of cream will cover the front and back of the body.
- If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.

Application of cream in children 1 year and older:
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult amount.
- A course of treatment for a child should not normally last more than 5 days - unless your doctor has told you to use it for longer. The doctor may want to see the child every week, whilst using the cream.

Children below 1 year

Clobaderm is contraindicated in children below 1 year.

Children are more susceptible to local and systemic adverse events caused by topical corticosteroids, and should generally be treated for a shorter duration and with less potent substances than adults. Clobetasol should be used with caution in children, to ensure that the smallest possible dose is applied within the therapeutic range.

4.3 Contraindications

- Rosacea
- Acne vulgaris
- Perioral dermatitis
- Perianal and genital pruritus
- Primary cutaneous viral infections (e.g. herpes simplex, chickenpox)
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- The use of ClobaDerm skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo)
- Dermatoses in children under one year of age, including dermatitis and napkin eruptions.

4.4 Special warnings and precautions for use

Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion. If /…/ is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.

If used in children or on the face, courses should be limited if possible to five days and occlusion should not be used.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If ClobaDerm does enter the eye, the affected eye should be bathed in copious amounts of water.

Visual disturbance
Visual disturbance may be reported with systemic and topical 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 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

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier

function of the skin. If used in psoriasis careful patient supervision is important.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. 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.

During application of corticosteroids on large areas, especially under (plastic) occlusion or in skin folds, increased absorption may occur, which could lead to adrenal function inhibition.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

ClobaDerm 0.5mg/g Cream contains cetostearyl alcohol which can cause local skin reactions (e.g. contact dermatitis), propylene glycol which may cause skin irritation and chlorocresol which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to humans has not been established, therefore, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

Breast-feeding
The safe use of clobetasol propionate during lactation has not been established.

It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk.

Administration of clobetasol propionate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation clobetasol propionate should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility
There are insufficient fertility data available to indicate whether clobetasol propionate has any effect on fertility.

4.7 Effects on ability to drive and use machines

ClobaDerm is not expected to have any effects.

4.8 Undesirable effects

The following adverse reactions have been identified during post-approval use of clobetasol propionate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The frequency of these adverse events has therefore been classified as “unknown”.

Immune system disorders
Hypersensitivity
- Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment.
- If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders
Features of Cushing's syndrome
- As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas can result in sufficient systemic absorption to produce the features of Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the nappy may act as an occlusive dressing.
- Provided the weekly dosage is less than 50g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

Eye disorders
- Vision, blurred (see also section 4.4)

Vascular disorders
Dilatation of the superficial blood vessels
- Prolonged and intensive treatment with highly-active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when skin folds are involved.

Skin and subcutaneous tissue disorders
Local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis.
- Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae.
- Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.
- Clobetasol may induce steroid-rosacea and steroid-acne.

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

4.9 Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, very potent, dermatological preparations (group IV), ATC code:

D07 AD01

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

5.2 Pharmacokinetic properties

Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0.5mg/g ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g clobetasol propionate cream 0.5mg/g mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.

In a separate study, mean peak plasma concentrations of approximately 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.5mg/g ointment.

Following percutaneous absorption of clobetasol propionate, the drug probably follows the metabolic pathway of systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys. However, systemic metabolism of clobetasol has never been fully characterised or quantified.

5.3 Preclinical safety data

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Glycerol monostearate
Arlacel 165 (glycerol monostearate & macrogol 100 stearate)
White beeswax
Propylene glycol
Chlorocresol
Sodium citrate
Citric acid monohydrate
Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years.
In-use shelf life: 3 months

6.4 Special precautions for storage

Store below 30 °C.

6.5 Nature and contents of container

Collapsible aluminum tubes internally coated with an epoxy resin based lacquer and closed with a polypropylene cap.

Pack sizes: 30g or 100g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Patients should be advised to wash their hands after applying ClobaDerm unless it is the hands that are being treated.

7 MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th July 2012

Date of last renewal: 24th May 2017

10 DATE OF REVISION OF THE TEXT

April 2018