SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Efcortelan Cream 1%
Hydrocortisone 1% Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 10 mg hydrocortisone (1 % w/w).

Excipient(s) with known effect
Each gram of cream contains 1 mg chlorocresol and 72 mg cetostearyl alcohol.
For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
A smooth white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone has topical anti-inflammatory activities of value in the treatment of a wide variety of dermatological conditions, including the following: eczema, including atopic, infantile, discoid and stasis eczemas; prurigo nodularis, neurodermatoses, seborrhoeic dermatitis, intertrigo and contact sensitivity reactions.
Hydrocortisone preparations can also be used in the management of insect bites and otitis externa.

Hydrocortisone 0.5% preparations can be used as continuation therapy in mild cases of seborrhoeic or atopic eczema once the acute inflammatory phase has passed.

4.2 Posology and method of administration

Posology

Adults, children and elderly
A small quantity should be applied to the affected area two or three times daily. Hydrocortisone cream is often appropriate for moist or weeping surfaces, and Hydrocortisone ointment for dry-lichenified or scaly lesions, but this is not invariably so.

Method of administration

For topical administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Skin lesions caused by infection with viruses (e.g. herpes simplex, chicken pox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo).

4.4 Special warnings and precautions for use

Long term continuous or inappropriate use of topical steroids can result in the development of
rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

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.

Paediatric population
In infants and children, long-term continuous topical therapy should be avoided where possible, as adrenal suppression can occur even without occlusion. In infants, the napkin may act as an occlusive dressing, and increase absorption. Treatment should therefore be limited, if possible, to a maximum of 7 days.

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.

As with all corticosteroids, prolonged application to the face is undesirable.

Fire hazard in contact with dressings, clothing and bedding
Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipients
This medicine contains chlorocresol and cetostearyl alcohol.
Chlorocresol may cause allergic reactions.
Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

The label will state mild steroid.

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 application of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human fetus.

4.7 Effects on ability to drive and use machines

Hydrocortisone skin preparations have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Eye disorders

Not known (cannot be estimated from the available data): Vision, blurred (see also section 4.4).

Skin and Subcutaneous Tissue Disorders

Not known (cannot be estimated from available data): Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

Hydrocortisone preparations are usually well tolerated but if signs of hypersensitivity appear, application should be stopped immediately.

Local atrophic changes may occur where skin folds are involved, or in areas such as the nappy area in small children, where constant moist conditions favour the absorption of hydrocortisone. Sufficient systemic absorption may also occur in such sites to produce the features of hypercorticism and suppression of the HPA axis after prolonged treatment.The effect is more likely to occur in infants and children, and if occlusive dressings are used.

There are reports of pigmentation changes and hypertrichosis with topical steroids.

Exacerbation of symptoms may occur.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, weak (group I). ATC code: D07AA02.

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects which suppress the clinical manifestations of the disease in a wide range of disorders where inflammation is a prominent feature.

5.2 Pharmacokinetic properties

Absorption
Hydrocortisone is absorbed through the skin particularly in denuded areas.

Biotransformation
Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol.

Elimination
Metabolites are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Cetomacrogol 1000
Cetostearyl alcohol
White soft paraffin
Liquid paraffin
Sodium acid phosphate
Phosphoric acid
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

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

Pack sizes: 15, 30 and 50 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Ltd
T/A Essential Generics
8a Crabtree Road
Egham
Surrey
TW20 8RN
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0091

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 18 December 1997
Date of latest renewal: 22 October 2004

10 DATE OF REVISION OF THE TEXT

16/10/2025