EFFICORT CREAM 0.127%

HYDROCORTISONE ACEPONATE

PRODUCT INFORMATION

1 COMPOSITION

Efficort Cream contains hydrocortisone aceponate 0.127% w/w as the active ingredient in an oil-in-water cream base containing selfemulsifying wax, white petrolatum, stearyl alcohol, benzyl alcohol and purified water.

2 PHARMACEUTICAL FORM

Efficort Cream is for cutaneous use only.

3 PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties: Efficort is a potent corticosteroid (class II) according to the European classification.
It acts on certain inflammatory and allergic processes occurring in the course of atopic and/or contact dermatitis and on pruriginous effects linked to these processes. It has a vasoconstrictor (anti-exudative) activity and it inhibits cellular replication and the synthesis processes in the dermis and epidermis.

Pharmacokinetic properties: Systemic absorption measured in terms of the effect on blood cortisol levels occurs after cutaneous application of Efficort.
The extent of absorption and of systemic effects depends on the area treated and the condition of the epidermis, the duration of the treatment: the more the treatment is prolonged, the greater the likelihood of these effects is, the site of application, the use of occlusive dressings.

Preclinical safety data: In animal studies, hydrocortisone aceponate was well tolerated on cutaneous application for periods of up to six months in rats and rabbits. The major symptoms of toxicity found in all animal species by systemic routes of administration were related to adrenocorticosteroid effects, and included alterations of the pituitary-adrenal axis, and a slight anemia. Principal organs of toxicity were the stomach, liver, adrenal, pituitary, lungs and spleen. In the cutaneous route studies hydrocortisone aceponate the majority of these findings were either absent or considerably reduced in magnitude.

4 INDICATIONS AND USAGE

Efficort is recommended for steroid-responsive dermatoses (eczema, atopic dermatitis, psoriasis, lichenification).
Efficort Cream is recommended for the treatment of acute exudative lesions.

5 CONTRA-INDICATIONS

Hypersensitivity to any ingredient of the preparation, ulcerated lesions, acne and rosacea and conditions for which cutaneous corticosteroid therapy is contra-indicated, notably skin infections of bacterial, viral, fungal and parasitic origin, even when these include an inflammatory response.

6 UNDESIRABLE EFFECTS

Cutaneous application of potent corticosteroids to large areas (30% of the body surface area or more) and/or over long periods (more than 2 weeks) may lead to onset of the following undesirable effects:

- Hair follicle inflammation (folliculitis), increased and intensified hair growth (hypertrichosis), skin bleaching (hypopigmentation), so-called steroid-acne and telangiectasia linear skin lesions (striae cutis distensae, striae atrophicae) affect-ing notably the limbs (occurring more usually in adolescents), cutaneous atrophy, post-atrophy ecchymoses and fragile skin.
- Disruption of the pituitary-adrenal axis on systemic uptake of the drug through the skin may also occur, particularly upon occlusive treatment of large areas.
- Corticosteroids may give rise to perioral dermatitis or create or aggravate rosacea of the face, wound healing may be impaired in the case of atonic wounds, sores, leg ulcers (see Contra-indications).

Potential systemic effects: see Special Warnings and Precautions for Use.
Blurred vision with the frequency not known (cannot be estimated from the available data). See Special Warnings and Precautions for Use.

7 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General: The prolonged use on the face of high-potency corticosteroids can give rise to a corticosteroid-induced dermatitis which is paradoxically corticosteroid-responsive. A rebound effect is observed at each interruption of treatment. Progressive and particularly difficult withdrawal is then required.
Due to the possibility of absorption of corticosteroids into the general circulation, treatment of large areas or under occlusion may give rise to the effects of systemic corticosteroid therapy, particularly in the infant and small child. These effects consist of Cushing syndrome and growth inhibition: these untoward effects disappear upon interruption of treatment but abrupt withdrawal can result in acute adrenal insufficiency. It is preferable to avoid use of corticosteroids in the infant and particular attention must be given to the likelihood of spontaneous occlusion. In the case of a bacterial or fungal infection of a corticosteroid-responsive dermatosis, either a specific antimicrobial treatment must precede the use of the corticosteroid or possibly, and in only certain cases, a combination of cortico-steroid plus specific treatment may be used.
If local intolerance occurs, treatment must be interrupted and the cause investigated.
In the event of application to the eyelid, the duration of treatment must be limited. Prolonged application exposes the patient to the risk of ptosis or glaucoma and a rebound effect can be observed.

Warnings and Precautions:

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 serious chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Adverse Reactions: Vision, blurred
Contact your doctor if you experience blurred vision or other visual disturbances.

Pregnancy and lactation: The use of Efficort during the first 3 months of pregnancy should be avoided unless the benefit outweighs any potential risks to the fetus.
It is not known whether this drug is excreted in animal or human milk. Because many drugs are excreted in human milk, caution should be exercised when Efficort is administered to nursing mothers. In this event, the product should not be used on the chest.

Overdose: Efficort is for cutaneous use only. If the medication is applied excessively, no more rapid or better results will be obtained and the undesirable effects described above may be increased and intensified.

8 INTERACTION WITH OTHER MEDICATIONS AND OTHER FORMS OF INTERACTION

Hydrolysis by alkaline agents: do not use alkaline antiseptics prior to applying Efficort.
Incompatibility with oxidative agents.

The concomitant use of other adrenocorticosteroids in the form of tablets, drops or injections may intensify the side effects.

9 DOSAGE AND METHOD OF ADMINISTRATION

Adults: Unless otherwise prescribed, Efficort should be applied once to twice daily in a thin layer over the affected skin areas.
For the application to be reasonable it is advisable to dab a small amount of product on to several sites at the affected areas and to gently massage in until it has been completely absorbed.
Application should be limited to twice a day. An increase in the number of daily applications would be likely to aggravate the side effects without improving the therapeutic efficacy of the preparation.
Treatment of large areas or long term therapy (3 weeks or more) require clinical monitoring. In any case the duration of treatment prescribed by the physician must be strictly observed. If required, an occlusive dressing could be prescribed by the physician.
In case of certain dermatological conditions (psoriasis, dermatitis, ...) a gradual withdrawal might be desirable. This may be achieved by reducing the frequency of application and / or the use of a more dilute or less potent corticosteroid.

Infants and young children: Unless otherwise prescribed, one daily application is generally adequate.
Continuous daily treatment should be limited to a short period (about 1 week). If used for a longer duration, period-ical steroid-free breaks should be interposed.
Occlusive dressings should be avoided in infants and young children.

Instructions for use / Handling: Squeeze the tube gently at its base to place a quantity of cream on the fingertips sufficient to cover the area to be treated. Wash hands thoroughly and replace cap tightly after use.

10 EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES

Based on the pharmacodynamic profile and extensive clinical experience, performance related to driving and using machines should not be affected.

11 SHELF LIFE

This medicine should not be used after the expiry date (Exp. Date) shown on the pack.

12 STORAGE

Store at or below 30°C. Keep out of reach of children.

13 CONTAINER

Efficort Cream is packed in 15g and 30g white polypropylene tubes fitted with white polypropylene screw caps. Not all presentations may be available locally.

Manufactured by:
Lichtenheldt GmbH Pharmazeutische Fabrik
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GERMANY

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