1. NAME OF THE MEDICINAL PRODUCT

Efficort Lipophilic Cream (hydrocortisone aceponate, 0.127 w/w).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Efficort Lipophilic Cream contains hydrocortisone aceponate 0.127% w/w as the active ingredient in a water-in-oil cream base containing white petrolatum, aluminium di/tristearate*, liquid paraffin, Protegin WX**, Cutina BW***, magnesium sulphate heptahydrate and purified water.

** Composition of aluminium di/tristearate:*
Aluminium salts and fatty acids (stearic and palmitic).

*** Compostion of Protegin WX:*
Mixture of mineral oil and white petrolatum, hydrogenated castor oil, glyceryl oleate and glyceryl isostearate and waxes of the ozokerite and ceresin types.

**** Composition of Cutina BW:*
Combination of waxy esters, high molecular weight fatty acids and partial glycerides of long chains fatty acids.

3. PHARMACOLOGICAL FORM

Efficort Lipophilic Cream is a lipophilic (water-in-oil emulsion) cream for cutaneous use.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Indications in which corticosteroid therapy is considered to be the best treatment: contact eczema, atopic dermatitis, lichenification.

- Indications in which cutaneous corticosteroid therapy is one of the usual treatments: stasis dermatitis ("varicose eczema"), psoriasis, lichen, non-parasitic prurigo, dyshidrosis, genital lichen sclerosus et atrophicus, annular granuloma, discoid lupus erythematosus, non-microbial palmoplantar pustuloses, extra-facial seborrhoeic dermatitis, symptomatic pruritus due to mycosis fungoides.

- Indications requiring short-term therapy: insect bites and parasitic prurigo after aetiological treatment.

Efficort Lipophilic Cream is recommended for the treatment of dry squamous inflammatory lesions.

4.2 Dosage and Method of Administration

Adults

Unless otherwise prescribed, **Efficort Lipophilic Cream** 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.

After improvement in the manifestations of the skin disease, frequency of applications may be reduced.

Infants and young children

Unless otherwise prescribed one application per day is generally adequate.

Continuous daily treatment should be limited to a short period (about one week). If used for a longer duration, periodical steroid-free breaks should be interposed.

Occlusive dressings should be avoided in infants and young children.

4.3 Contra-indications

. Hypersensitivity to any ingredient of the preparation
. Ulcerated lesions
. Acne and rosacea
. 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.

4.4 Special Warnings and Precautions for Use

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's 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 corticosteroid 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.

4.5 Interaction with other Medications and Other Forms of Interaction

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

4.6 Pregnancy and Lactation

The use of **Efficort Lipophilic Cream** during the first 3 months of pregnancy should be avoided unless the benefit outweighs any potential risks to the foetus.

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 Lipophilic Cream** is administered to nursing mothers. In this event, the product should not be used on the chest.

4.7 Effects on 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.

4.8 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 teleangectases, linear skin lesions (striae cutis distensae, striae atrophicae) affecting 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**).

4.9 Overdose

Efficort Lipophilic Cream 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Efficort Lipophilic Cream 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.

5.2 Pharmacokinetic Properties

Systemic absorption measured in terms of the effect on blood cortisol levels occurs after cutaneous application of **Efficort Lipophilic Cream**.

The extent of absorption and of systemic effects depends on the:

- area treated and condition of the epidermis,
- duration of treatment: the more the treatment is prolonged, the greater the likelihood of these effects is,
- site of application,
- use of occlusive dressings.

5.3 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 anaemia. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Efficort Lipophilic Cream contains white petrolatum, aluminium di/tristearate, liquid paraffin, Protegin WX, Cutina BW, magnesium sulphate heptahydrate and purified water.

6.2 Incompatibilities

None known.

6.3 Shelf-life

3 years

6.4 Special Precautions for Storage

Store at a temperature not exceeding 25°C.
Keep out of reach of children.

6.5 Nature and Contents of Containers

Efficort Lipophilic Cream is packaged in 30 g collapsible aluminium tubes coated internally with an epoxy-phenolic type resin and fitted with white polypropylene screw caps.

6.6 Instructions for Use / Handling

Squeeze the tube gently as 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.