

## **Hydrocortisone Butyrate**

***Hydrocortisone 17-butyrate 0.1% w/w topical cream***  
***Hydrocortisone 17-butyrate 0.1% w/w topical ointment***

### **Presentation**

A smooth white cream containing 0.1% w/w hydrocortisone butyrate.

An ointment containing 0.1% w/w hydrocortisone butyrate in a polyethylene and mineral oil base.

### **Uses**

#### ***Actions***

Hydrocortisone 17-butyrate is a synthetic corticosteroid with anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties and is indicated in the topical treatment of a variety of acute and chronic skin disorders. Therapeutically effective concentrations of the corticosteroid are obtained in the skin tissues by percutaneous absorption or penetration resulting in a rapid anti-inflammatory and anti-pruritic effect. Hydrocortisone Butyrate Cream is therefore suitable for the treatment of eczemas and dermatitis characterized by primary or secondary efflorescences which have been found to respond to corticosteroid treatment, e.g. psoriasis, lichen simplex.

#### ***Pharmacokinetics***

Percutaneous penetration of corticosteroids varies between patients and can be increased by the use of occlusive dressings, increasing the concentration of the corticosteroid or by using different vehicles.

Once absorbed through the skin, topical corticosteroids follow pharmacokinetic pathways similar to systemically administered corticosteroids. Hydrocortisone 17-butyrate is metabolised primarily by the liver to hydrocortisone and other metabolites. These and traces of the unmetabolised hydrocortisone butyrate are excreted via the urine or bile.

#### ***Indications***

Treatment of conditions responsive to topical corticosteroids e.g. eczema, dermatitis and psoriasis.

### **Dosage and Administration**

#### **Adults and Children**

Apply to the affected areas 1 to 4 times daily or as directed by the physician.

Once daily administration is associated with a slower rate of skin clearance and may therefore be recommended in cases where considerations of convenience and/or compliance arise.

An occlusive dressing may be applied when necessary.

For the treatment of chronic disorders with formation of scales, dry skin lesions and skin lesions with fissures and seborrhoea the ointment will be preferred.

In acute, very moist skin disorders it may be necessary to use the cream.

## **Contraindications**

- Skin lesions caused by:
  - bacterial infections (e.g. pyodermias, luetic and tuberculous processes)
  - viral infections (e.g. varicellae, herpes simplex, herpes zoster, verrucae vulgares, verrucae planae, condylomata, mollusca contagiosa)
  - mycotic and yeast infections
  - parasitic infections (e.g. scabies)
- Ulcerous skin lesions, wounds
- Adverse reactions induced by corticosteroids (e.g. dermatitis perioralis, striae atrophicae)
- Ichthyosis, juvenile dermatosis plantaris, acne vulgaris, acne rosacea, fragility of the skin vessels, skin atrophy
- Allergic hypersensitivity to components of the vehicle or to corticosteroids (the latter rarely occurs).

## **Warnings and Precautions**

Hydrocortisone Butyrate Cream contains parabens, which may have a sensitizing effect. In case of hypersensitivity to any of the ingredients of the preparation treatment should be stopped.

Co-existing infection may require specific chemotherapy or withdrawal of therapy.

When steroids, and particularly fluorinated steroids, are applied to large areas of the body (about 10% and more) and/or for long periods of time (more than four weeks) the occurrence of atrophic striae is likely especially if an occlusive dressing is used.

Prolonged use on the flexures is undesirable. Adrenal suppression can occur, even without occlusion.

With daily use of 15g or more over long periods, especially under occlusion, systemic absorption may occur. At such a time routine steroid precautions must be observed if the patient is stressed, e.g. as in surgery. Adrenal suppression is more likely to occur in infants and children.

In children the application of topical steroids should be limited as much as possible. Inhibition of the adrenal function may occur rather rapidly. In addition, inhibition of growth hormone excretion may occur. If long-term treatment is necessary, it is therefore advisable to check length and weight as well as the plasma cortisol level regularly. Babies and children up to four years should not be treated longer than 3 weeks. In infants the napkin may act as an occlusive dressing and increase absorption.

The skin of the face, pilous skin and the skin of the genitals are particularly sensitive to corticosteroids; it is therefore desirable to treat these areas primarily only with weak corticosteroids.

Do not apply on the eyelids because of the possibility of contamination of the conjunctiva, with the risk of inducing glaucoma simplex or a subcapsular cataract.

## ***Use during Pregnancy and Lactation***

In pregnant animals, administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for long periods.

Corticosteroids are known to pass through the placenta and may therefore influence the foetus. This will be mainly of significance, however, in case of an intensive treatment of large surfaces with a potent or very potent product. In animal tests corticosteroids were demonstrated to be teratogenic.

It is not known whether corticosteroids absorbed through the skin may be demonstrated in mother's milk.

#### ***Effects on ability to drive and use machines***

There are no data available on the effect of hydrocortisone-17-butyrate on the ability to drive and use machines, but no effects are to be expected.

### **Adverse Effects**

#### **Local Effects**

- Skin atrophy, often irreversible, with thinning of the epidermis, telangiectasias, purpura and striae
- Rosacea-like and perioral dermatitis with or without skin atrophy
- "Rebound effect", which may lead to dependence on steroids
- Delay of the wound healing process
- Effects on the eye: increased intraocular pressure, increased chance of a cataract
- Depigmentation, hypertrichosis
- Contact allergy

The incidence of local adverse reactions increases with the strength of the product and the duration of treatment. Application under occlusion (plastic, skin folds) increases this risk.

- The skin of the face, pilous skin and the skin of the genitals are especially sensitive to local effects.
- If used incorrectly, bacterial, parasitic, fungal and viral infections may be masked and/or aggravated.

#### **Systemic Effects**

Systemic effects as a consequence of topical application of corticosteroids in adults rarely occur, but may be serious.

Inhibition of the adrenal cortex may especially be of importance in long-term treatment.

Hypersensitivity has been reported in the literature but the incidence is unknown.

The risk of systemic effects is highest in:

- Application under occlusion (plastic, skin folds)
- Application on large surfaces
- Long-term treatment
- Application in children (the thin skin and the relatively large surface of the skin make children very sensitive)
- Presence of components or excipients which increase the penetration through the stratum corneum and/or the effect e.g. propylene glycol

### **Interactions**

No data are available.

**Overdosage**

There are no data available on an overdose of Hydrocortisone Butyrate. In case of chronic overdose, symptoms of hypercorticism might occur.

**Pharmaceutical Precautions**

Store below 25 °C.

**Medicines Classification**

Prescription Only Medicine

**Package Quantities**

Cream: Tubes of 10g, 15g, 30g and 45g

Ointment: Tubes of 10g, 15g, 30g and 45g

**Further Information**

Hydrocortisone butyrate is a non-fluorinated topical steroid. Whilst clinical trials have shown it to be as effective as the potent fluorinated steroids, in clinical practice there is a low incidence of reported clinical side-effects.

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