

Hydrocortisone cream 10 mg/g, cream

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Therapeutic indications

- Superficial, non-microbial skin conditions (to prevent masking) sensitive to corticosteroids, such as: Eczema (dermatitis) of various origins (atopic eczema, orthoergic contact dermatitis, seborrheic eczema, varicose eczema)
- Localized forms of pruritus (such as pruritus ani)
- Localized forms of prurigo
- Maintenance or aftertreatment of skin conditions previously suppressed with a stronger product.
- Occlusion may be necessary to achieve a better therapeutic result.

Dosage and method of administration

Initially, apply the cream twice a day in a thin layer to the affected skin area, then once a day after a few days. After improvement, 2 to 3 times a week is usually sufficient.

Contraindications

Skin conditions caused by: Bacterial infections (such as pyodermas, syphilitic and tuberculous processes), Viral infections (such as varicella, herpes simplex, herpes zoster, verrucae vulgaris, verrucae planae, condylomata, mollusca contagiosa), Fungal and yeast infections, Parasitic infections (such as scabies).

Ulcerative skin conditions, wounds.

Side effects due to corticosteroids (such as perioral dermatitis, atrophic striae).

Ichthyosis, juvenile plantar dermatosis, acne vulgaris, acne rosacea, fragility of the skin vessels, skin atrophy.

Allergic hypersensitivity to corticosteroids or to components of the vehicle.

Special warnings and precautions for use

Do not apply to the eyelids due to the possibility of contamination of the conjunctiva with the risk of developing simplex glaucoma or subcapsular cataract.

The facial skin, hairy skin and genital skin are particularly sensitive to corticosteroids; therefore, it is desirable to treat conditions in these areas primarily with weak corticosteroids, such as Hydrocortisone cream 10 mg/g.

When applying corticosteroids to large surfaces, especially under (plastic) occlusion or in skin folds, be aware of the strong possibility of absorption through the skin and the potential for adverse reactions.

Interactions with other medicinal products and other forms of interaction: There are no known interactions with other medicinal products or other forms of interaction.

Pregnancy and lactation: Corticosteroids are known to pass the placenta and can, therefore, affect the fetus. However, this will mainly be significant with intensive treatment of large areas with a strong or very strong product. Corticosteroids have been shown to be teratogenic in animal tests. Only use during pregnancy in consultation with your doctor.

Effects on ability to drive and use machines: There is no information available about the effect of this product on driving ability. However, an effect is not expected.

Side effects

- Local effects
- The most frequent side effects are:
- Thinning of the epidermis and dermis
- Perioral dermatitis
- Atrophic striae
- Telangiectasia, tendency to bleed
- Less frequent side effects are:
- Depigmentation
- Transition of psoriasis to psoriasis pustularis
- Masking of parasitic, fungal, and bacterial infections
- Rare side effects are:
- Hypertrichosis
- Colloidal milia
- Increased ocular pressure
- Erythrosis interfollicularis colli
- Contact allergy
- Granuloma gluteale

The risk of local side effects increases with the strength of the product. Application under occlusion (plastic, skin folds) increases this risk. The face, hairy skin, and genital skin are particularly sensitive to local effects.

Systemic effects

Systemic side effects resulting from local application of corticosteroid preparations are rare but can be serious. Suppression of the adrenal cortex can be of particular importance with prolonged use. The risk of systemic effects is greatest with:

- Application under occlusion (plastic, skin folds)
- Application on large skin surfaces
- Application in children (the thin skin and relatively large skin surface make children very sensitive).

Overdose: In case of overdose on the skin, reference can also be made to possible side effects as mentioned under 4.8.

Pharmacological Properties

Pharmacodynamic properties

Hydrocortisone acetate has anti-inflammatory and vasoconstrictive effects, suppresses the inflammatory response and symptoms of various often pruritic conditions, however, without curing the underlying conditions. In the distribution of dermal corticosteroids according to Avery's potency classification, this product belongs to the weakly active corticosteroids. The effect can be enhanced by applying an occlusive dressing due to increased penetration (by a factor of approximately 10) of the stratum corneum. However, the risk of side effects increases as a result.

Pharmacokinetic properties

Approximately 1-3% of the administered dose of hydrocortisone is absorbed by normal skin. The absorption in eczematous skin is approximately twice that amount, while absorption in severely inflamed skin can be up to five times the normal value. In children, absorption decreases with increasing age.

Preclinical safety data

No specific concerns.

Pharmaceutical Particulars

List of excipients: Cetylstearyl alcohol, cetomacrogol 1000, decyloleate, non-crystallizable sorbitol 70%, sorbic acid (preservative, 2mg/g), and purified water.

Incompatibilities: Not applicable.

Shelf life: The shelf life in an aluminum tube is 3 years. The shelf life after opening the tube is 1 year. The shelf life in a polypropylene flask is 2 years. The shelf life after opening the flask is 1 year.

Special precautions for storage: Store below 25°C in the tightly closed original packaging. If stored in this way, the cream is stable until the date stated on the packaging.