SUMMARY OF THE PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrokortison Evolan, 10 mg/g, cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains 10 mg hydrocortisone.

Excipients with known effect:
Cetostearyl alcohol 72 mg, methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White to yellow-white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute and chronic eczema of varying genesis. Anogenital pruritus.

4.2 Posology and method of administration

The cream should be thinly applied in the morning and evening. When the symptoms are under control the number of applications can usually be decreased and alternated with emollient therapy.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Contact with the eyes should be avoided.
Should not be applied in open wounds.
As with all corticosteroids for external use, care should be taken when treating large body areas and during long-term treatment.
Hydrokortison Evolan cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and parahydroxybenzoic esters which may cause allergic reactions (possibly delayed).
Children under 2 years should only be treated with Hydrokortison Evolan if prescribed by a doctor.
Treatment duration should not be more than 4-6 weeks, unless the patients are under regular supervision by physician.
In case of concomitant infection, an appropriate antifungal or antibacterial agent needs to be administered.
The risk for local adverse events is reduced if hydrocortisone is used without occlusion.

Topical corticosteroids are not suitable for treatment of perioral dermatitis, rosacea and acne vulgaris.

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.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to hydrocortisone is negligible. Hydrokortison Evolan can be used during pregnancy. However, prolonged use and large amounts of cream should be avoided.

Breastfeeding
Hydrocortisone is excreted in human milk, but at therapeutic doses of Hydrokortison Evolan no effects on the breastfed newborns/infants are anticipated. Hydrokortison Evolan can be used during breast-feeding. However, prolonged use and large amounts of cream should be avoided.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Side effects can be expected in approximately 1% of patients. Cases of sensitisation caused by hydrocortisone are rare, but have been reported.

Skin and subcutaneous tissue disorders:
Uncommon (>1/1,000, <1/100): Irritation, contact dermatitis
Cases of allergic contact dermatitis (hydrocortisone) have been reported.

Eye disorders:
Uncommon (>1/1,000, <1/100): Vision, blurred (see also section 4.4)

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 national reporting system listed in Appendix V

4.9 Overdose

Overdose is not expected, since the cream is intended for external use. If the cream has nevertheless accidentally been ingested, undertake supporting measures as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC-code: D07AA02
Pharmacotherapeutic group: corticosteroids, weak (Group 1)

Hydrocortisone is a group I steroid with an anti-inflammatory and antipruritic effect.

5.2 Pharmacokinetic properties

Glucocorticoids have the ability to penetrate stratum corneum of the epidermis and affect the deeper cell layers. Usually only a small proportion of the dose is absorbed, and it is thus not expected to affect the hormonal balance. The systemic effect of glucocorticoids can occur in the event of increased absorption, e.g. when applied on large inflamed areas of skin, or on skin of which the stratum corneum of the epidermis is damaged. Occlusive bandages increase absorption.

5.3 Preclinical safety data

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

cetostearyl alcohol
macrogol cetostearyl ether
light liquid paraffin
white soft paraffin
citric acid (E330)
sodium citrate (E331)
methyl parahydroxybenzoate (E218)
ethyl parahydroxybenzoate (E214)
propyl parahydroxybenzoate (E216)
water

6.2 Incompatibilities

Not relevant.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

No special storage instructions.

6.5 Nature and content of container

20 g, 50 g and 100 g in aluminium-laminated plastic tubes in outer box.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Evolan Pharma AB
Box 120
182 12 Danderyd
Sweden

8 SVERIGE MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 Dec 1990
Date of latest renewal: 21 Dec 2010

10 DATE OF REVISION OF THE TEXT

2023-11-15