

SUMMARY OF THE PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrokortison Evolan, 10 mg/g, Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g ointment contains 10 mg hydrocortisone.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White to greyish-white homogeneous ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute and chronic eczema of varying genesis. Anogenital pruritus.

4.2 Posology and method of administration

The ointment should be 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.

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 ointment should be avoided.

Lactation

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

- 4.9 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](#) Overdose**

Overdose is not expected, since the ointment is intended for external use. If the ointment 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. Hydrokortison Evolan ointment is suitable for conditions involving dry and flaking skin.

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

Light liquid paraffin
White soft paraffin

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 Instructions for use and handling, and disposal (if appropriate)

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Evolan Pharma AB
Box 120
182 12 Danderyd
Sverige

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 Dec 1990 / 21Dec 2010

10 DATE OF REVISION OF THE TEXT

2021-02-01