

Momecort

Dermal Cream & Ointment



Composition:

Each 1 g of Momecort Dermal Cream or Ointment contains Mometasone Furoate 1 mg.

Pharmacological Classification:

Topical Corticosteroid.

Intended Use (Common Use of the Drug):

Treatment of steroid-responsive dermatitis.

Mechanism of Action:

Mometasone furoate exhibits marked anti-inflammatory and anti-psoriatic activity in standard animal predictive models.

Pharmacokinetics:

Pharmacokinetic studies have indicated that systemic absorption following topical application of Mometasone Furoate as ointment or cream 0.1% is minimal, approximately 0.7% of the applied dose in man, the majority of which is excreted within 72 hours following application.

Indications:

This medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.

Momecort is used to treat of inflammatory skin conditions which respond to external treatment with glucocorticoids, such as atopic dermatitis and psoriasis (excluding widespread plaque psoriasis).

Contraindications:

Momecort is contraindicated in the following conditions: acne, skin atrophy, perioral dermatitis, pruritus around the anus and genitals, nappy rash, bacterial or viral infections (such as herpes simplex), parasitic and fungal infections (such as candida), tuberculosis, syphilis, wounds or ulcers. It is also contraindicated in patients who are allergic to mometasone furoate or other corticosteroids or to any of the ingredients of the preparation.

Side Effects:

Like all medicines, this one can cause side effects, although not everyone experiences them.

- Side effects with unknown frequency: infection, furuncle, parasthesia, contact dermatitis, hypopigmentation, hirsutism, striae, acneiform dermatitis, skin atrophy, pain at the application site, reactions at the application site.

- Rare local side effects reported with topical corticosteroids include: dry skin, irritation, dermatitis, perioral dermatitis, maceration of the skin, heat rash and telangiectasia.

- Paediatric patients: Paediatric patients may be more susceptible to topical corticosteroid stimulation of hypothalamic-pituitary-adrenal-axis suppression and Cushing's syndrome than adult patients due to their larger skin surface area to body weight ratio. Chronic corticosteroid therapy may interfere with the growth and development of children.

Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & Precautions:

- If irritation or sensitivity occurs, treatment should be discontinued and appropriate therapy instituted.

- In case of skin infection, an appropriate antifungal or antibacterial agent should be used. If a satisfactory response does not occur immediately, corticosteroids should be discontinued until the infection is adequately controlled.

- Systemic absorption of topical corticosteroids can result in reversible suppression of the hypothalamic pituitary-adrenal-axis with the potential for glucocorticoid insufficiency after treatment is withdrawn.

- Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface area relative to body mass.

- Local and systemic toxicity is common, particularly following prolonged, continuous use over large areas of damaged skin, in flexures and with polyethylene dressings.

- Topical corticosteroids can be dangerous in psoriasis for a

number of reasons including the risk of relapses following the development of tolerance, the risk of central pustular psoriasis and the development of local or systemic toxicity due to impaired skin function.

- As with all potent topical glucocorticoids, abrupt discontinuation of treatment should be avoided.

- Glucocorticoids may alter the appearance of some lesions, making it difficult to establish a proper diagnosis and may also delay healing.

- Mometasone Furoate topical preparations are not intended for ophthalmic use, including the eyelids, due to the very rare risk of developing simple glaucoma or subcapsular cataracts.

Drug and Food Interactions:

Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

Co-administered drugs that inhibit CYP3A (e.g., cobicistat, ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose of the corticosteroid and the potency of the CYP3A inhibitor.

Pregnancy & Lactation & Fertility:

Pregnancy: Pregnancy category C. Momecort should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or fetus.

Lactation: It is not known whether topical corticosteroids can result in sufficient systemic absorption to appear in appreciable amounts in breast milk. Momecort should be used in breast-feeding women only after careful consideration of the benefit/risk relationship.

Fertility: Its effect on fertility has not been studied after topical application in humans.

Effects on ability to drive and use machines:

Momecort has no or negligible influence on the ability to drive and use machines.

Method of use:

- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

- A thin film should be applied to the affected areas of skin once daily. Use of a weaker corticosteroid is often advisable when there is a clinical improvement.

- Use of topical corticosteroids on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

Adults: Momecort should not be used for long periods (over 3 weeks) or on large areas (over 20% of body surface area).

Children aged 2 years and older: In children aged 2 years and older a maximum of 10% of body surface area should be treated. Treatment duration is limited to a maximum of 3 weeks.

Children below 2 years of age: It should not be used in children below 2 years of age, as efficacy and safety have not been established.

Overdoses/Toxicity/methods of treatment:

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

Physical Properties:

White to off-white, smooth, uniform, free from foreign matter Cream or Ointment.

Storage Conditions:

Store at a temperature below 30° C.

Keep out of reach of children.

Keep tube tightly closed.

The cream or ointment can be used for up to 3 months after opening the package for the first time.

Packaging:

Each Momecort Cream or Ointment carton box contains Aluminum Tube of 20 g.

-A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICATIONS OUT OF REACH OF CHILDREN
Council of Arab Health Ministries - Union of Arab Pharmacies

Revva Pharma for Pharmaceutical Industries - Idlib - Syria

PO1401 / R02

