

Product information leaflet

COMPOSITION: Active ingredients: Mometasone furoate. Excipients: **MOVESAN cream:** White Soft paraffin , Propylene Glycol Monostearate, Hexylene Glycol, Titanium Dioxide, Stearyl Alcohol & Cetareth 20, Aluminium Starch Octenylsuccinate, Water Purified and Phosphoric Acid for pH regulation. **MOVESAN cut solution:** Isopropanol, Propylene Glycol, Hyprolose, Sodium Phosphate Monobasic, Water Purified and Phosphoric Acid for pH regulation.

PHARMACEUTICAL FORM: MOVESAN cream - MOVESAN cut. sol.

CONTENT IN ACTIVE INGREDIENTS: • 1g of MOVESAN cream contains 1mg Mometasone Furoate. • 1g of MOVESAN cut.sol. contains 1mg Mometasone Furoate.

DESCRIPTION-PACKAGING: MOVESAN cream: Aluminum tube containing 25g of white-off white smooth cream with polyethylene safety cap.

MOVESAN cut solution: Plastic bottle containing 30 ml of colourless to slightly yellowish cutaneous solution.

PHARMACOTHERAPEUTIC GROUP: Corticosteroids (ATC : D07AC13)

MARKETING AUTHORISATION HOLDER & MANUFACTURER: IASIS PHARMA HELLAS S.A, 137, Filis Ave, 13451 Athens, GREECE. Tel: +30 210 23 11 031

THINGS THAT YOU SHOULD KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

GENERAL INFORMATION: Mometasone furoate is a synthetic corticosteroid, with anti-inflammatory, antipruritic and vasoconstrictive properties.

INDICATIONS: MOVESAN cream & cut.sol are indicated for the relief from inflammatory and pruritic manifestations of dermatopathies responding to potent topical corticosteroids such as : • Psoriasis (other forms excluding plaque psoriasis, palmar-plantar psoriasis and reverse psoriasis) / • Atopic eczema / • Nummular eczema / • Contact dermatitis / • Mastocytosis / • Lupus erythematosus / • Parapsoriasis / • Alopecia areata

MOVESAN cut.sol can also be used on scalp lesions.

CONTRAINDICATIONS: MOVESAN cream & cut.sol are contraindicated in patients sensitive to Mometasone furoate, to other corticosteroids or to any other ingredient of the product. Topical corticosteroids should not be used in case of undiagnosed skin condition. Also, their use should be avoided in cases of acne, perioral dermatitis in leg ulcers, and burns because they hinder healing.

SPECIAL WARNINGS & PRECAUTIONS FOR USE:

GENERAL: a. Avoid a long-term use in children. Children and adolescents are more prone to systemic adverse effects with topical corticosteroids, because greater amounts of the drug may be absorbed, due to greater skin surface area relative to body weight. Also, long-term therapy should be avoided in infants and toddlers.

b. When applying occlusive dressing, patients should be advised to clear their skin to avoid possible contamination.

c. Do not use topical corticosteroids beyond 3 weeks without review by a dermatologist.

d. After repeated application, at least 10-15 days, temporary decrease or loss of efficacy of corticosteroids (especially fluorinated) due tachyphylaxis can be observed. This phenomenon is restored after stopping use for a few days or weeks.

e. In psoriasis corticosteroids can be granted sparingly and with supervision of an expert, because beyond the temporary benefit, there is a risk of worsening disease long-term after the discontinuation of therapy .

f. Due to adverse effects from possible absorption caution is required, when applied to large surfaces of skin or in prolonged administration especially in children and patients with severe kidney disease, bleeding diathesis and upcoming vaccinations.

g. Generally, the less potent corticosteroid that is effective for the intended indication should be chosen and on non-reaction another of the same or greater potency should be administered.

h. MOVESAN may cause cataracts and glaucoma when used in the area of the eyes for prolonged periods. If you use the medicine topically to eyelids, caution is required so as the drug not to come into contact with the eye.

If irritation or sensitisation appears due to the use of MOVESAN, treatment should be discontinued and appropriate therapy should be instituted. Avoid use under occlusive dressings.

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Any of the reported undesired effects due to the systemic use of corticosteroids, including adrenal suppression may also occur when using topical corticosteroids, particularly in neonates and children.

Systemic absorption of topical corticosteroids will increase if extended body areas are subject to treatment or if used under occlusive dressings. In these cases or when a prolonged therapy is expected, special precautions must be taken particularly in neonates and children. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal axis suppression and Cushing's syndrome than adult patients, because of a larger skin surface area to body weight ratio.

Topical corticosteroid use in children must be reduced to the minimum therapeutic result including quantities. Prolonged therapy with corticosteroids, may affect children growth.

MOVESAN cream & cut.sol preparations are not for ophthalmic use.

PREGNANCY: The safety of MOVESAN (cream & cut.sol) in pregnant women has not been established scientifically. For this reason, topical corticosteroids may be administered during pregnancy only if the potential benefit justifies the potential risk to the foetus.

The active substances which belong to this category should not be used in large quantities and for prolonged periods in pregnant women.

There are insufficient data on safety of topical corticosteroids when used in pregnant women. Topical administration of potent corticosteroids to pregnant animals has caused abnormalities in fetal development. For this reason, topical corticosteroids may be administered during pregnancy only if the potential benefit justifies the potential risk to the foetus. In such cases, topical corticosteroids should not be administered in large quantities or for long periods.

LACTATION: It is not known whether topical use of corticosteroids may result in systemic absorption in such levels that can be detected in the breast milk. Systemically administered corticosteroids are secreted to the breast milk in quantities that are not likely to be harmful to the foetus. In any case, the doctor shall decide on either breast feeding or treatment discontinuation, taking into consideration the significance of the medicine administration for the mother.

When corticosteroid use during breast feeding is necessary, the quantities of medication and duration of therapy should be minimized.

CHILDREN : The use of topical corticosteroids to children should be limited to the minimum amount that will have maximum therapeutic effect. Chronic treatment with corticosteroids can affect children's development.

EFFECT ON THE ABILITY TO DRIVE AND USE MACHINES: Not reported.

SPECIAL WARNINGS REGARDING THE EXCIPIENTS: Do not administer the medicine to patients who have previously demonstrated hypersensitivity to any of the excipients.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS OR SUBSTANCES: Interactions of the active substance (mometasone furoate) with other medicinal products or substances are not reported. There is also not any known interaction for the overall category of corticosteroids.

POSOLOGY AND METHOD OF ADMINISTRATION: • MOVESAN cream: Apply a thin layer of Movesan cream on the skin affected areas once daily.

• MOVESAN cut solution: Apply a few drops (4-6) of Movesan cutaneous solution on the skin or scalp affected areas once daily and rub the area well with soft moves until the drug is absorbed.

OVERDOSE: Symptoms: The extensively prolonged use of topical corticosteroids may suppress the adrenocortical function resulting in secondary adrenocortical insufficiency.

Treatment: Appropriate treatment is indicated. Acute hypercortical symptoms are basically reversible. Treat electrolyte imbalance if necessary. In case of chronic toxicity gradual treatment interaction is indicated.

UNDESIRABLE EFFECTS: Local side effects **very rarely** reported with MOVESAN include paraesthesias, itching and signs of skin atrophy.

The following adverse reactions due to the use of other corticosteroids have been **rarely** reported: irritation, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Topical after long term topical use: The undesirable effects that have been reported with potent topical corticosteroids in their positions of application are: Burning, itching, irritation, dryness, folliculitis, hypopigmentation, thinning skin, telangiectasias.

Modification of clinical presentation on misuse (fungal infections, scabies).

Secondary infection, local bacterial infection (latent infection initiation or aggravation evolving), fungal infections, facilitating the entry of molluscum contagiosum and genital warts.

Inhibition of wound healing, acne, pustules, heat rash, perioral dermatitis, rash in the form of acne rosacea, relapse of pustular psoriasis on treatment discontinuation (Rebound Phenomenon), skin atrophy in form of scar, linear streaks, spider veins, purple rash, diffuse erythema, atypical papillo-vesicular rashes, allergic hypersensitivity, localized hypertrichosis.

If symptoms of hypersensitivity appear, the administration should be stopped immediately.

These side effects are not common, but may occur more frequently with the use of occlusive dressings or after long-term topical use.

General after long-term topical use: Suppression of the function of adrenal-cortical axis, lowering of plasma cortisol level - CUSHING syndrome.

IF YOU MISS A DOSE: Should the medicine be administered uninterruptedly and you have missed a dose, you should take the missed dose as soon as possible. If the appropriate time for the next dose administration is close, do not take the dose you have missed, but continue normal treatment instead.

EXPIRATION DATE OF THE PRODUCT: It is indicated on the outer and inner packaging. Do not use this drug after the expiration date.

SPECIAL PRECAUTIONS FOR STORAGE: MOVESAN cream and MOVESAN cut.sol must be stored at temperatures lower than 25° C

DATE OF LAST PRODUCT INFORMATION LEAFLET REVISION: 07/2012

INFORMATION ON THE RATIONAL USE OF DRUGS

• This medicine was prescribed by your doctor for your specific health problem. You should not administer it to others or use it yourself for other health problems, without prior consent from your doctor.

• Inform immediately your doctor or pharmacist if a problem appears during the treatment.

• If you have any questions regarding the medicine that you are taking or you need further information on your health problem, do not hesitate to contact your doctor or pharmacist and ask for additional information.

• The medicine that was prescribed to you is safe and effective only when administered according to your doctor or pharmacist instructions.

• It is important for your safety and your health to read carefully all information regarding the medicine that was prescribed to you.

• Do not store medicines in bathroom closets since heat and humidity may alter them and render them hazardous for your health.

• Do not store medicines that have already expired or are no more useful to you.

• For more safety keep medicines in a secure place away from children

MODE OF ADMINISTRATION: This medicine may only be administered with a doctor's prescription