

PATIENT INFORMATION LEAFLET

1. DETERMINATION OF THE MEDICINAL PRODUCT

1.1 Name: Movithiol

1.2 Composition:

Active ingredient: Betamethasone (as Betamethasone 17-valerate).

Excipients: Calbomer 934, Sodium hydroxide, Isopropyl alcohol, Purified water.

1.3 Pharmaceutical form: Lotion in isopropyl alcohol solution.

1.4 Content: 1 ml of lotion contains 1.210 mg betamethasone valerate, corresponding to 1 mg or 0.1% betamethasone.

1.5 Description – Packaging: 50 ml Plastic vial , containing transparent and colourless solution with a dropper cap, in a cardboard box with a patient leaflet.

1.6 Pharmacotherapeutical group: Corticosteroid for topical use.

1.7 Marketing Authorisation Holder– Manufacturer: IASIS PHARMA HELLAS S.A
137, Filis Ave., 134 51 Kamatero Attikis, Greece. Tel: +30 210 2311031

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

2.1 General information

Betamethasone valerate at content of 0.1%, is classified to the potent topical corticosteroids, regarding its activity.

2.2 Therapeutic Indications

Dermatoses of the scalp responding to steroids such as:

- Psoriasis
- Seborrhea of the scalp
- Inflammation associated with severe head dandruff.

The potential topical corticosteroids are indicated for:

- Psoriasis (other forms excluding plaque psoriasis, palmar-plantar psoriasis and reverse psoriasis)
- Atopic eczema
- Nummular eczema
- Contact dermatitis
- Mastocytosis
- Lupus erythematosus
- Parapsoriasis
- Alopecia areata

2.3 Contraindications

- Infections of the scalp
- The use of Movithiol lotion is not recommended in skin diseases in children aged less than 1 year, including dermatitis.
- Hypersensitivity to any component of the product.
- Topical corticosteroids should not be used in case of undiagnosed skin condition and also in case of microbial, fungal or viral skin infections, in cases of acne, perioral dermatitis, in ulcers, and burns because they hinder healing.

2.4 Special warnings and precautions for use

2.4.1 General

Avoid long-term use in children. Children are more prone to systemic adverse effects with topical corticosteroids, because larger amount of the drug may be absorbed, due to greater skin surface area relative to body weight.

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

Do not use topical corticosteroids for longer than 3 weeks without a follow -up by a dermatologist.

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.

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

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.

Generally, the less potent corticosteroid that is effective for the intended indication should be chosen and in case of poor results, another of the same or higher potency-class should be administered.

Movithiol lotion 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 that the medicine does not contact the eye.

2.4.2 Pregnancy and lactation

Topical corticosteroids may be administered during pregnancy only according to the judgment of the physician and 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. When corticosteroid use during breast feeding is necessary, the dosage and duration of therapy should be minimized.

2.4.3 Effects on ability to drive and use machines

None known.

2.4.4 Children

See posology and special precautions.

2.5 Interaction with other medicinal products and other forms of interaction:

None known.

2.6 Posology and method of administration

A small amount of Movithiol lotion is placed on the scalp at night and morning, until improvement, which is then maintained by using Movithiol lotion once a day or even less often.

2.7 Overdose – Treatment

Acute overdose is unlikely to happen, however in case of chronic overdosage or misuse, the characteristics of overactive adrenal cortex may occur, and in this situation topical steroids should be discontinued gradually. However, because of the risk of acute adrenal suppression, this should be done under medical supervision.

2.8 Undesirable effects

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.

Alteration 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 after 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.

An exacerbation of symptoms may be caused.

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 levels – CUSHING syndrome.

2.9 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. **Do not double the doses.**

2.10 Expiration of the product

It is indicated on the outer and inner packaging. Do not use this drug after the expiration date.

2.11 Special precautions for storage

Movithiol lotion must be stored at temperature not exceeding 25°C, protected from light and moisture.

2.12 Date of last product information leaflet revision: 7-2-2003

3. 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

4. MODE OF ADMINISTRATION

This medicine may only be administered with a doctor's prescription