PRENIDERM ®
0.1% Cream

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PRENIDERM
PRENIDERM cream is a topical preparation containing 0.1% methylprednisolone aceponate with the following excipients: glyceryl monostearate, cetostearyl alcohol, vaseline, benzalkonium chloride, glycerin, and purified water.
Methylprednisolone aceponate is a potent topical corticosteroid sharing anti-allergic, anti-inflammatory, and anti-proliferative properties. It relieves topical symptoms such as redness, edema, infiltration, lichenification, itching, burning, and pain.
PRENIDERM is indicated for the relief of symptoms associated with constitutional eczema (atopic dermatitis, neurodermatitis), ordinary eczema, allergic and irritative contact eczema, eczema due to dyshidrosis, and infantile eczema.

The way to use PRENIDERM
Use according to your doctor's instructions.
Wash and dry your hands before using. Clean and dry the affected area. Apply a thin film of medication to the affected area and gently rub in, usually once daily or as directed by your doctor. Do not bandage, cover, or wrap the area unless directed to do so by your doctor.

Duration of treatment
The duration of treatment will be decided by your doctor.
Treatment with PRENIDERM should not be longer than 12 weeks in adults and 4 weeks in children.

In case of overdose
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.
If you suspect an overdose, irritation develops, or if the cream has been ingested, inform your doctor at once and seek emergency medical attention.
Treatment must be discontinued if skin atrophy develops after a topical overdose.

In case of missed dose
Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications
This drug is contraindicated in the following conditions:
- Hypersensitivity to any of the components
- Patient suffering from tuberculosis, or syphilis in the area to be treated, from virus diseases (e.g. chickenpox, herpes zoster), and post-vaccination skin reactions in the area to be treated.
- Acne, rosacea, perioral dermatitis, open wounds, ulcers, skin atrophy, furuncles, and abscess.

Precautions

-This medication is for external use only. Avoid contact with the eyes, open wounds, and all mucous membranes. If contact occurs, rinse thoroughly with water.

-Don't use this medication for any disorder other than for which it was prescribed or for longer than the prescribed time period.

- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by your doctor.

- Notify your doctor if the condition being treated is not responding to the treatment or if the condition gets worse. Report any signs of local adverse reactions.

- Do not increase the number of applications without consulting your doctor. More frequent applications may increase the risk of side effects without ameliorating the therapeutic effects.

- In the presence of skin infections, the use of an appropriate antifungal or antibacterial agent should be instituted.

- Inform your doctor if you have glaucoma.

- Consult your doctor before using this medication in case of pregnancy or lactation. The use of this drug should be decided by the doctor in case of absolute necessity.

- The safety and efficacy of this drug in pediatric patients less than 4 months of age have not been established. Children may be more susceptible to topical corticosteroid-induced systemic toxicity than adults. Do not use for children without medical advice.

Associations with other medications

Please inform your doctor if you are using any other medication. Do not put cosmetics or other skin products over the treated area unless directed by your physician. You should avoid preparations that may dry or irritate your skin. Other corticosteroid containing products should not be used with this cream without first talking to your doctor.

Adverse reactions

The most reported adverse reactions include burning and itching.

Other reported adverse reactions include: dermatomycosis, pyoderma, acneic symptoms, vesicles, folliculitis, skin fissures, stretch marks, telangiectasia, skin atrophy, irritation, dryness, erythema, edema, striae, perioral dermatitis, changes in skin color, hypertrichosis, cellulite, cutaneous allergic reactions, rash, and paraesthesia.

The use over large surface areas, prolonged use and the addition of occlusive dressings increase systemic absorption of topical corticosteroids and the risk of systemic side effects.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (below 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation

PRENIDERM, methylprednisolone aceponate 0.1% cream, tube of 20 grams

Issue date: 11/2013

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