Dermatop® Cream
Prednicarbate

SANOFI

Composition
Each gram of cream contains, as active ingredient, 2.5 mg prednicarbate in an oil-in-water emulsion.

Excipients: Benzyl alcohol, octyldodecanol, light liquid paraffin, stearyl alcohol, cetyl alcohol, myristyl alcohol, polysorbate 60, sorbitan stearate, disodium edetate, purified water.

Properties
The prednicarbate in Dermatop Cream is an active corticosteroid specially developed for topical application. It has pronounced antiinflammatory, antiexudative and antipruritic effects. The cream is particularly suitable for treating acute and/or weeping skin disorders.

Indications
Skin diseases, where treatment with topical corticosteroids is appropria te. In such skin disorders, Dermatop Cream is also suitable for sensitive areas of skin and for repeated application.Use in large areas must be under direct supervision of a doctor.

Contraindications
Dermatop Cream must not be used on the eyes (see also under "Special warnings and precautions") and in patients with hypersensitivity to prednicarbate or any of the excipients (see under "Composition").
Dermatop Cream contains a paraffin, which can cause leaking or breaking of latex condoms. Contact between Dermatop Cream and latex condoms must , therefore, be avoided, because the protection afforded by the condoms may otherwise be lost.

Patients with skin reactions resulting from vaccinations, cutaneous manifestations of tuberculosis, syphilis, viral infections (for example chickenpox), rosacea, and perioral dermatitis, must not use topical corticosteroids such as Dermatop Cream, because there is a risk that the condition may deteriorate.

Pregnancy and lactation:
Application of Dermatop Cream over extensive areas (more than 30% of the body surface) is contraindicated during the first three months of pregnancy, since systemic glucocorticoid effects cannot be excluded. However, if there are compelling medical reasons, Dermatop Cream may be applied to small areas of skin.
Caution should be exercised when Dermatop cream is administered to nursing women.
Insufficient clinical experience is available on use during lactation.

Special warnings and precautions
Dermatop Cream must only be used in infants if there are compelling medical reasons, since the risk of systemic effects due to corticosteroid absorption (for example growth retardation) cannot be excluded. If use is unavoidable, application must be limited to the minimum dose required for successful treatment.
Over the course of time, increased intra-ocular pressure can develop if small doses of topical corticosteroids (to include Dermatop Cream) come into repeated contact with the conjunctival sac. For this reason, prolonged application of Dermatop Cream in the immediate vicinity of the eyes must be preceded by a careful risk-benefit assessment and must only be performed under medical supervision.
Topical corticosteroids such as Dermatop Cream must only be used for symptomatic therapy of bacterial and/or mycotic skin infections in combination with concomitant antibacterial or antimycotic treatment.

Avoid long term usage because it can increase the possibility of systemic absorption.
Visual disturbance may be associated 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)

Adverse effects
The following CIOMS frequency rating is used, when applicable:
Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1 and < 1%; Rare ≥ 0.01 and < 0.1%; Very rare < 0.01%; Not known (cannot be estimated from available data).
In approximately 2 - 3 % of patients a burning sensation and, in rare cases, itching, folliculitis or allergic skin reactions with e.g. burning, reddening or weeping may occur. Skin atrophogenic effects (such as skin thinning, skin atrophy, skin discoloration, telangiectasia) may occur with use of the *TM* for more than three weeks. (frequency: not known)

Eye disorders: blurred vision4, chorioretinopathy

Please consult a physician if you notice any of the adverse effects listed in this package insert or any other undesired effects or unexpected changes (for example new skin changes).

Dosage and administration
Dosage is generally based on the following guidelines and is determined by the physician in accordance with individual requirements:

Dermatop Cream is applied to the affected skin areas in a thin layer once daily, and, if possible, rubbed in gently. If necessary, the frequency of use may be increased to twice daily.

Long-term continuous treatment should not exceed 4 weeks.

Dosage mistakes: Short-term deviations from the scheduled dose (application over too large an area or in excessive amounts, too frequent application, or a single missed dose) will not lead to harmful effects. Please consult your physician if these occur.

Storage
Store below 30º C.

Expiry date
Do not use later than the date of expiry.

Keep medicines out of the reach of children.

This package insert is continually updated:
please read carefully before using a new pack!

Presentation
Tube containing :
5 g Reg.No.DKL0121202829A1
15 g Reg.No.DKL0121202829A1

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

Manufactured by:
PT Aventis Pharma,
Jakarta, Indonesia

SAP / ID. number : PACKING INSERT DERMATOP CREAM (SA)-2 / 544705
Country : Indonesia
Version number : 1
Date : 10.04.2018
Dimensions : 105 x 150 mm
Logo version : Sanofi - aventis
Version A1 - 03.02.2006
Film code : SA/544705
Min. point size of text : 8 pt
Colour ■ : Pantone Reflex Blue CVC
Material : HVS Paper 60 g/m2
Type of prefolded : 3x Horizontal
Pharmacode : 47051
Dimensions after folded : 105 mm X 19 mm
Position of Pharmacode : 45-45.5mm, 46.5-47mm, 48-49.5mm, 50.5-52mm, 53-53.5mm, 54.5-55mm, 56-57.5mm, 58.5-60mm, 61-62.5mm, 63.5-65mm, 66-67.5mm, 68.5-69mm, 70-71.5mm, 72.5-74mm, 75-75.5mm
Prepared by : Rahmat Hafid & Azka Afina

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ID : EREG10002212200246
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544705 - PACKING INSERT DERMATOP CREAM (SA)-2

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Packaging material name:	PACKING INSERT DERMATOP CREAM (SA)-2
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VISTAlink folder number:	4044426
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