PRESCRIBING INFORMATION

PrPROPADERM®
Beclomethasone Cream, BP
Cream, 0.025% w/w Beclometasone Dipropionate, Topical

Topical Corticosteroid

Bausch Health, Canada Inc.
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Laval, Quebec
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December 10, 2020

Control #: 242212

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ACTION AND CLINICAL PHARMACOLOGY

PROPADERM (beclomethasone dipropionate) is a potent anti-inflammatory steroid. In the vasoconstriction test on human skin, beclomethasone dipropionate is five thousand times as potent as hydrocortisone.

Clinical studies
It has been shown in clinical trials that the optimal concentration of beclomethasone dipropionate cream is 0.025% w/w.

In two hundred and sixty-seven patients, PROPADERM and fluocinolone acetonide were used simultaneously in a double-blind fashion. There was no significant difference in the action of the two substances. No side-effects or toxic reactions were reported.

One patient discontinued treatment due to the development of a pruritic eruption during medication with another formulation of PROPADERM (previously marketed lotion).

INDICATIONS AND CLINICAL USES

PROPADERM is indicated for all skin conditions where a topical anti-inflammatory steroid is indicated, including psoriasis, eczema, allergic dermatoses, neurodermatitis, seborrhea, intertrigo, lichen simplex, lichen planus, discoid lupus erythematosus and anogenital pruritus.

CONTRAINDICATIONS

Infected skin lesions if no anti-infective agent is used simultaneously; fungal and viral infections of the skin, including herpes simplex, vaccinia and varicella; pregnancy; hypersensitivity to any of the ingredients. Topical corticosteroids are also contraindicated in tuberculous lesions of the skin.

WARNINGS

PROPADERM should not be used in the eye. When topical anti-inflammatory steroids are used under occlusive dressing, over extensive areas, it is possible that sufficient absorption may take place to give rise to systemic effects. Such effects have not been reported with PROPADERM.

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

ADVERSE REACTIONS

Local burning, irritation, itching, skin atrophy, striae, hypertrichosis and adrenal suppression have been observed following topical corticosteroid therapy. Posterior subcapsular cataracts have been reported following the systemic use of corticosteroids.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Discontinuation of therapy, when the typical signs of hypercorticisim appear.

DOSAGE AND ADMINISTRATION

PROPADERM is applied thinly to cover the affected area and gently rubbed in. Application is usually one to three times daily or as indicated by the severity of the condition. In certain resistant dermatoses the effect of PROPADERM can be enhanced if the treated area is covered with an occlusive dressing using impermeable material such as polyethylene film of cellophane.

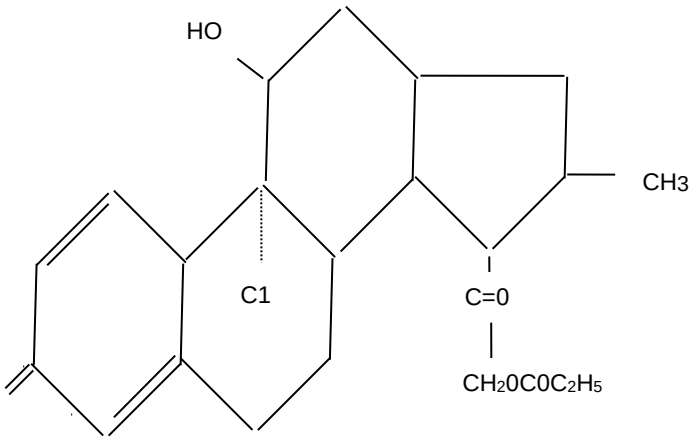
PHARMACEUTICAL INFORMATION

Drug Substance

Common Name: Beclomethasone Dipropionate

Chemical Name: 9α-chloro-11β-hydroxy-16β-methyl-17α, 21-dipropionyl-oxy-pregna-1, 4-diene-3, 20-dione

Structural Formula:



Molecular Formula: $C_{28}H_{37}ClO_7$.

Molecular Weight: 521.04 g/mol

STABILITY AND STORAGE RECOMMENDATION

PROPADERM: store between 15° and 25°C

AVAILABILITY OF DOSAGE FORMS

PROPADERM: each gram of cream contains beclomethasone dipropionate 0.025% w/w.

Available in tubes of 45 g, and 120g.

REFERENCES

1. Caldwell IW, Hall-Smith SP, Main RA, Ashurst PJ, Kirton V, Simpson WT, Williams GW. Clinical evaluation of a new topical corticosteroid beclomethasone dipropionate. Br J Dermatol 1968; 80:111.

2. Fine S, Hewitt R, Hodge DID, Lustman F, Simpson EAD. A trial of beclomethasone dipropionate in general practice. Practitioner 1968; 201:362.

3. Raffle EJ, Frain-Bell W. The effect of topically applied beclomethasone dipropionate on adrenal function. Br J Dermatol 1967; 79:487.

4. Raffle EJ, Frain-Bell W. The effect of topically applied beclomethasone. Br J Dermatol 1968; 80:124.