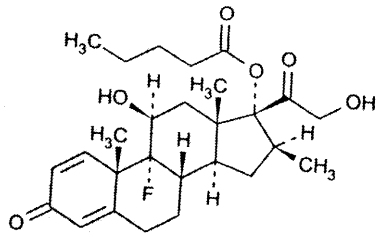
PRODUCT INFORMATION
CELESTONE-M CREAM

NAME OF THE MEDICINE

Betamethasone valerate

Chemical Structure:



Betamethasone valerate is 9-fluoro-11β,21-dihydroxy-16β-methyl-3,20-dioxopregna-1,4-dien-17-yl pentanoate. The empirical formula is $C_{27}H_{37}FO_6$. MW = 476.6

DESCRIPTION

Celestone-M Cream contains betamethasone valerate equivalent to betamethasone 0.2mg, chlorocresol 1 mg/g as preservative, soft white paraffin, liquid paraffin, cetostearyl alcohol, cetomacrogol 1000, sodium phosphate monobasic, phosphoric acid and purified water.

PHARMACOLOGY

Betamethasone valerate is a topically-active corticosteroid ester with anti-inflammatory, antipruritic and vasoconstrictive actions.

INDICATIONS

Celestone-M is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses such as atopic eczema, infantile eczema, nummular eczema, anogenital and senile pruritus, contact dermatitis, seborrhoeic dermatitis, neurodermatitis, solar dermatitis, stasis dermatitis and psoriasis.

Celestone-M is indicated for the maintenance therapy.

CONTRAINDICATIONS

Hypersensitivity to betamethasone valerate, other corticosteroids or any components in Celestone-M. Like other topical corticosteriods, Celestone-M is contraindicated in most viral infections of the skin, such as vaccinia, varicella and Herpes simplex, also tuberculosis and acne rosacea.

PRECAUTIONS

Celestone-M should not be used in or near the eyes.

If irritation or sensitisation develops with the use of Celestone-M, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur promptly, Celestone-M should be discontinued until the infection has been controlled adequately.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Use in Pregnancy (Category A)

Topical corticosteroids should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.

Use in Lactation

Due to lack of data on the safety of betamethasone valerate in lactation, care should be exercised to ensure that the potential benefits to the lactating mother outweigh the possible hazards to the nursing infant.

Paediatric use

Chronic corticosteroid therapy may interfere with the growth and development of children. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilaterial papilloedema.

ADVERSE EFFECTS

The following local adverse reactions have been reported with the use of topical corticosteroids: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Rarely reported adverse effects include tingling, prickly skin/tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema and telangiectasia.

DOSAGE AND ADMINISTRATION

Apply a small amount to the affected area two or three times daily.

Refractory lesions of psoriasis and other deep seated dermatoses, such as chronic lichen simplex, hypertrophic lichen planus, atopic dermatitis, chronic eczematous and lichenified hand eruptions, recalcitrant pustular eruptions of the palms and soles, respond better if occlusive dressings are used.

Occlusive Dressings

Apply a layer of medication over the entire lesion under a light gauze dressing, cover with a pliable transparent, impermeable plastic material well beyond the edges of the treated area. Seal the edges to normal skin by adhesive tape or other means. Leave the dressing in place for 1 to 3 days and repeat the procedure three or four times as needed. Occasionally, a miliary eruption or folliculitis develops in the skin beneath the dressing and should be treated by removing the plastic covering and applying a topical antibiotic.

OVERDOSAGE

Symptoms

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease.

Treatment

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

PRESENTATION AND STORAGE CONDITIONS

Celestone-M Cream, 0.02% (0.2 mg/g): 100g
Store below 25° C

NAME AND ADDRESS OF THE SPONSOR

Merck Sharp & Dohme (Australia) Pty Limited
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Macquarie Park NSW 2113
Australia

POISON SCHEDULE OF THE MEDICINE

Prescription Only Medicine (Schedule 4)

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOOD

Cream: 8 October 1991

DATE OF MOST RECENT AMENDMENT: 24 September 2015