

pharmaniaga®



Dermasole

Cream / Ointment

Betamethasone (as 17-valerate) 0.1%

DESCRIPTION

Pharmaniaga Dermasole Cream

A white, soft cream, free from foreign matter.

Pharmaniaga Dermasole Ointment

A clear translucent ointment.

COMPOSITION

Each gram of Dermasole Cream or Ointment contains Betamethasone (as 17-valerate) 1 mg (0.1% w/w).

Also contains Chlorocresol 0.1% w/w as preservative.

PHARMACODYNAMICS

Pharmacodynamic properties

ATC Code: D07 AC01 Corticosteroid, potent, (group III)

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents by multiple pathways to prevent allergic reactions in the late phase including decreasing mast cell density, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting arachidonic acid metabolism.

Pharmacodynamic effects

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

PHARMACOKINETICS

Absorption

Topical corticosteroids can be absorbed systemically from intact healthy skin. The extent of percutaneous absorption

of topical corticosteroids is determined by several factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other skin disease processes may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints to assess systemic exposure of topical corticosteroids is necessary because the levels of circulation are well below the level of detection.

Metabolism

Upon absorption through the skin, topical corticosteroids pharmacokinetic mechanisms is similar to corticosteroids that are administered systemically. They are metabolised mainly in the liver.

Elimination

Topical corticosteroids are excreted by the kidney. Some corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS

Betamethasone is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following:

- Atopic dermatitis (including infantile atopic dermatitis)
- Nummular dermatitis (discoid eczema)
- Prurigo nodularis
- Psoriasis (excluding widespread plaque psoriasis)
- Lichen simplex chronicus (neurodermatitis) and lichen planus
- Seborrhoeic dermatitis.
- Irritant or allergic contact dermatitis
- Discoid lupus erythematosus
- Adjunct to systemic steroid therapy in generalised erythroderma
- Insect bite reactions
- Miliaria (prickly heat)

CONTRAINDICATIONS

Dermasole is contraindicated in pruritus without inflammation, perianal and genital pruritus, rosacea, acne, perioral dermatitis, untreated cutaneous infection and in dermatoses in infants under one year of age, including dermatitis.

WARNING AND PRECAUTIONS

Dermasole should be used with caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions may resemble symptoms of the condition under treatment.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency.

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing)
- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face
- Use on broken skin or other conditions where the skin barrier may be impaired
- In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Visual disturbance has been reported by patients using systemic and/or topical corticosteroids. If a patient has blurred vision or other visual disturbances, consider evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy.

Children

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in psoriasis

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalized pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Application to the face

Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure.

Concomitant infection

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the

148.5mm

210mm

148.5mm

dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

PREGNANCY AND LACTATION

Administration of betamethasone valerate during pregnancy and lactation should only be considered if the expected benefit to the mother outweighs the risk to the foetus or infant.

Pregnancy

There are limited data from the use of Dermasole in pregnant women. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development.

The relevance of this finding to humans has not been established. However, the minimum quantity should be used for the minimum duration.

Lactation

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk.

If used during lactation betamethasone valerate should not be applied to the breasts to avoid accidental ingestion by the infant.

**ADVERSE REACTIONS
Infections and Infestations**

Very rare: Opportunistic infection

Immune System Disorders

Very rare: Local hypersensitivity

Endocrine Disorders

Very rare: Hypothalamic-pituitary adrenal (HPA) axis suppression Cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis.

Skin and Subcutaneous Tissue Disorders

Common: Pruritus, local skin burning /skin pain

Very rare: Allergic contact dermatitis /dermatitis, erythema, rash, urticaria, pustular psoriasis, skin thinning* / skin atrophy*, skin wrinkling*, skin dryness*, striae*, telangiectasias*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms.

*Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.

General Disorders and Administration Site Conditions

Very rare: Application site irritation/pain

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

There have been no studies to investigate the effect of betamethasone valerate on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical betamethasone valerate.

DOSAGE AND ADMINISTRATION

Adults, Elderly and Children over 1 year

Creams are especially appropriate for moist or weeping surfaces. Ointments are especially appropriate for dry, lichenified or scaly lesions. Apply thinly and gently rub in using only enough to cover the entire affected area once or twice daily for up to 4 weeks until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Dermasole can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions; thereafter, improvement can usually be maintained by regular application without occlusion.

If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.

Atopic dermatitis (eczema)

Therapy with Dermasole should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy. Rebound of pre-existing dermatoses can occur with abrupt discontinuation of Dermasole.

Recalcitrant dermatoses

Patients who frequently relapse

Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (once daily, twice weekly, without occlusion) may be considered. This has been shown to be helpful in reducing the frequency of relapse.

Application should be continued to all previously affected sites or to known sites of potential relapse. This regime should be combined with routine daily use of emollients. The condition and the benefits and risks of continued treatment must be re-evaluated on a regular basis.

Children

Dermasole is contraindicated in children under one year of age. Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults. Care should be taken when using Dermasole to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Clinical studies have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment

In case of systemic absorption when application is over a large surface area for a prolonged period, metabolism and elimination may be delayed therefore increasing the risk of systemic

toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

DRUG INTERACTIONS

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

OVERDOSAGE

Symptoms and signs

Topically applied betamethasone valerate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur.

Treatment

In the event of overdose, Dermasole should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

ROUTE OF ADMINISTRATION

Topical.

STORAGE CONDITIONS

Store below 30°C.

Keep container tightly closed. Protect from light.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION

Pharmaniaga Dermasole Cream

Tubes of 15g.

Pharmaniaga Dermasole Ointment

Tubes of 15g.

In jar of 500g (for hospital tender only).

Date of revision: 01 March 2024

PRODUCT REGISTRATION HOLDER:

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