Package Insert

Jardin®

Jardin Betacream 0.0125% Betamethasone Valerate 0.0125% w/w Cream

Description
Jardin Betacream 0.0125% Betamethasone Valerate 0.0125% w/w Cream is a white, soft cream and free from foreign matter containing Betamethasone (as valerate) 0.0125% w/w.

Pharmacodynamics/Pharmacokinetics
Jardin Betacream 0.0125% Betamethasone Valerate 0.0125% w/w Cream contains betamethasone (as valerate), an active corticosteroid with topical anti-inflammatory, antipruritic and vasoconstrictive properties.
Topical corticosteroid can be absorbed through skin. Skin with inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings on the skin increase percutaneous absorption and substantially increase the percutaneous absorption of corticosteroid.
Topical corticosteroid follow the same pharmacokinetic pathways similar to systemically administered corticosteroid. Corticosteroid are bound to plasma proteins in varying degrees and are metabolised primarily by the liver and excreted by the kidneys.

Indications
Betamethasone valerate readily diluted preparations are indicated for maintenance treatment once an acute episode has been treated effectively with a continuous course of betamethasone valerate 0.1% w/w.
- Eczema including atopic, infantile and discoid eczemas.
- Prurigo nodularis.
- Psoriasis (excluding widespread plaque psoriasis).
- Neurodermatoses including lichen simplex, lichen planus.
- Seborrhoeic dermatitis.
- Contact sensitivity reactions.
- Discoid lupus erythematosus.
- An adjunct to systemic steroid therapy in generalised erythroderma.
- Insect bite reactions.

Recommended Dosage
Adults, Elderly and Children over 1 year
Creams are especially appropriate for moist or weeping surfaces.
Once an acute episode has been treated effectively with a continuous course of betamethasone valerate, improvement may be maintained with a small amount of readily diluted betamethasone valerate applied once or twice a day. Allow adequate time for absorption after each application before applying an emollient.
If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.
Therapy with betamethasone valerate 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 betamethasone valerate.

Children
Betamethasone valerate 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; therefore, courses should be limited to five days and occlusion should not be used.
Care should be taken when using betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly
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.

Mode Of Administration
Topical application.

Contraindications
- Rosacea, acne vulgaris, perioral dermatitis and use in widespread plaque psoriasis.
- Primary cutaneous viral infections (e.g herpes simplex, chickenpox).
- Hypersensitivity to any ingredient of the preparation.
- Primarily infected skin lesions caused by infections with fungi (e.g. candidiasis, tinea); or bacteria (e.g. impetigo); primary or secondary infections due to yeast; peri-anal and genital pruritus; dermatoses in children under 1 year of age, including dermatitis and napkin eruptions.

Warnings and Precautions
- Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency.
- The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.
- If used in childhood, or on the face, courses should be limited to five days and occlusion should not be used.
- Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.
- Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.
- In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease. Jardin Betacream 1:8 cream is usually well tolerated but if signs of hypersensitivity appear, application should stop immediately. Exacerbation of symptoms may occur.
- There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

Interactions With Other Medications
None known.

Usage During Pregnancy And Lactation
Inadequate evidence of safety in pregnant women. Topical application of corticosteroid to pregnant animals can cause birth defects especially when applied in large amount. There is a small risk that same effect may occurs in human fetus. It is therefore advisable to avoid extensive use of corticosteroid during pregnancy.
The safe use of topical betamethasone valerate during lactation has not been established.
Consult doctors before using the product.

Adverse Effects / Undesirable Effects
Immune system disorders
Very rare : Hypersensitivity
If sign of hypersensitivity appear, application should stop immediately.

Endocrine disorder
Very rare: features of Cushing's syndrome.
As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce suppression of the hypothalamic-pituitary-adrenal axis and the clinical features of Cushing's syndrome. (These effects are more likely to occur in infants and children and if occlusive dressings are used. In infants the napkin may act as an occlusive dressing).

Skin and subcutaneous tissue disorders
Common: Local skin burning and pruritus.
Very rare: Local atrophic changes in the skin such as thinning, striate and dilation of the superficial blood vessels (telangiectasia) may be caused by prolonged and intensive treatment with potent corticosteroid preparations, particularly when occlusive dressing are used or when skin folds are involved. Pigmentation changes, hypertrichosis, allergic contact dermatitis, exacerbation of symptoms, pustular psoriasis (due to treatment of psoriasis with corticosteroid or its withdrawal).

Overdose And Treatment
Acute overdosage is very unlikely to occur. However in case of chronic overdosage or misuse, the features of Cushing's syndrome may appear and in this situation, topical corticosteroid should be discontinued gradually under medical supervision.

Storage Conditions
Keep tube tightly closed.
Store below 30 °C.
Keep medicine out of reach of children.
Controlled Medicine.

Dosage Forms And Packaging
Cream. Tube 15 gram.

Shelf Life
24 months.

This insert contains basic prescribing information only. For further information, please consult your physician or pharmacist.

Product Registration Holder
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