

DATA SHEET

BETA

Betamethasone Valerate Cream and Ointment

Presentation

BETA Cream: A white, soft, homogeneous cream containing 0.1% w/w betamethasone as the valerate ester.

BETA Ointment: A soft, smooth, translucent ointment containing 0.1% w/w betamethasone as the valerate ester.

Uses

Actions

Betamethasone valerate is an active topical corticosteroid which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and is often effective in the less responsive conditions such as psoriasis.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroid is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily by the liver and are then excreted by the kidneys.

Indications

BETA preparations are indicated for the treatment of: 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; insect bite reactions; prickly heat; and they may be used as an adjunct to systemic steroid therapy in generalised erythroderma.

Dosage and Administration

A small quantity of BETA should be applied to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day, or even less often.

BETA Cream is especially appropriate for moist or weeping surfaces and BETA Ointment for dry, lichenified or scaly lesions, but this is not invariably so.

In the more resistant lesions, such as the thickened plaques of psoriasis on the elbows and knees, the effect of BETA 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.

Contraindications

- Rosacea, acne vulgaris and peri-oral dermatitis.
- Perianal and genital pruritus.
- Skin lesions caused by primary infection with viruses (e.g. vaccinia, herpes simplex, chickenpox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo) and ulcerative conditions.
- Hypersensitivity to any component of BETA preparations.
- Dermatoses in children under one year of age, including dermatitis and napkin eruptions.
- The use of fluorinated corticosteroids is contraindicated on the face.

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 corticosteroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency (see Adverse Effects and Overdosage). 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 and systemic administration of antimicrobial agents. 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.

The least potent corticosteroid, which will control the disease, should be selected.

Use in Pregnancy and Lactation

There is inadequate evidence of safety in humans. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intrauterine growth retardation. There may be a very small risk of such effects in the human foetus.

Adverse Effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1000$) and very rare ($< 1/10,000$) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The background rates in placebo and comparator groups were not taken into account when assigning frequency categories to adverse

events derived from clinical trial data, since these rates were generally comparable to those in the active treatment group. Rare and very rare events were generally determined from spontaneous data.

Immune system disorders

Very rare: Hypersensitivity.

If signs of hypersensitivity appear, application should stop immediately.

Endocrine disorders

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 HPA axis and the clinical features of Cushing's syndrome (see Warnings and Precautions). 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, striae and dilatation of the superficial blood vessels may be caused by prolonged and intensive treatment with highly active corticosteroid preparations, particularly when occlusive dressings 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 corticosteroids or its withdrawal: see Warnings and Precautions).

Interactions

None known.

Overdosage

Acute overdosage is very unlikely to occur. However, in the case of chronic overdosage or misuse, the features of Cushing's syndrome may appear and in this situation topical corticosteroids should be discontinued gradually under medical supervision (See Warnings and Precautions).

Pharmaceutical Precautions

Store below 25°C.

Medicine Classification

Prescription Medicine.

Package Quantities

BETA Cream and Ointment: Tubes of 30g, 50g or 100g.

Not all pack sizes may be marketed.

Further Information

Excipients in BETA Cream: white soft paraffin, cetostearyl alcohol, liquid paraffin, cetareth 20, monobasic sodium phosphate, sodium hydroxide, purified water, and chlorocresol as preservative.

Excipients in BETA Ointment: white soft paraffin, white beeswax, propylene glycol and stearyl alcohol.

BETA Ointment and Cream do not contain lanolin or parabens.

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