Ezex®

Clobetasone Butyrate BP

COMPOSITION

Ezex® 0.05 % Cream : Each gm cream contains 0.5 mg Clobetasone Butyrate BP.
Ezex® 0.05 % Ointment : Each gm ointment contains 0.5 mg Clobetasone Butyrate BP.

PHARMACOLOGY

Clobetasone Butyrate is a topically active corticosteroid, which provides an exceptional combination of activity and safety. It is more effective in the treatment of eczemas than 1% Hydrocortisone, or the less active synthetic steroid preparations that are in common use. It has little effect on hypothalamic-pituitary-adrenal function. All topical corticosteroids can cause cutaneous atrophy if grossly misused. However, study in animal and human models indicates that Clobetasone Butyrate causes less thinning of the epidermis than the other topical steroid tested.

INDICATION

Ezex® preparations are indicated for the treatment of eczema and dermatitis of all types including atopic eczema, photodermatitis, otitis externa, primary irritant allergic dermatitis (including napkin rash), intertrigo, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions.
Ezex® may be used as a maintenance therapy between courses of one of the more active topical steroids.

DOSAGE AND ADMINISTRATION

Apply to the affected area up to four times a day until improvement occurs, when the frequency of application may be reduced.

CONTRAINDICATION AND PRECAUTION

Skin lesions caused by infection with viruses (e.g. herpes simplex, chicken pox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo), hypersensitivity to the preparations.
Although generally regarded as safe, even for long-term administration in adults, there is a potential for overdosage, and in infants and children this may result in adrenal suppression. Extreme caution is required in dermatoses in such patients including napkin eruption (as the napkin may act as an occlusive dressing and increase absorption) and treatment should not normally exceed seven days.
Clobetasone Butyrate
Topical corticosteroid
Ezex®
Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions, which have infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents.
As with all corticosteroids, prolonged application to the face is undesirable.
Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, and risk of generalized toxicity due to impaired barrier function of the skin. If used in psoriasis, careful patient supervision is important.
If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as glaucoma might result.

SIDE EFFECT

In the unlikely event of signs of hypersensitivity appearing, application should stop immediately. When large areas of the body are being treated with Clobetasone Butyrate, it is possible that some patients will absorb sufficient steroid to cause transient adrenal suppression despite the low degree of systemic activity associated with Clobetasone Butyrate.
Local atopic changes could possibly occur in situations where moisture increases absorption of Clobetasone Butyrate, but only after prolonged use.
There are reports of pigmentation changes and hypertrichosis with topical steroids.
Exacerbation of symptoms may occur.

DRUG INTERACTION

Potentially hazardous interactions- none has been reported.
Potentially useful interactions- none has been reported.

USE IN PREGNANCY AND LACTATION

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

OVERDOSE

Acute overdosage is very unlikely to occur, in the case of chronic

Manufactured by

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