

New Zealand Datasheet

Name of Medicine

CLOBEX[®] Shampoo

Clobetasol propionate 0.05% w/w

Presentation

CLOBEX Shampoo contains 0.05% w/w clobetasol propionate. CLOBEX Shampoo is a viscous, translucent, colourless to pale yellow liquid shampoo with an alcoholic odour.

Uses

Actions

Clobetasol propionate is a very active topical corticosteroid which is of particular value when used in short courses for conditions which do not respond satisfactorily to less active steroids.

Like other topical corticosteroids, CLOBEX 0.5 mg/g Shampoo has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of topical corticosteroids in general is unclear. However, corticosteroids are thought to act by induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Pharmacokinetics

Percutaneous penetration of clobetasol propionate varies among individuals and as with other topical corticosteroids, sufficient clobetasol propionate may be absorbed to give systemic effects especially if applied under an occlusive dressing or when the skin is broken. The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier and occlusion. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and other disease processes in the skin may increase percutaneous absorption. There are no human data regarding the distribution of corticosteroids to body organs following topical application. Nevertheless, once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys. Clobetasol propionate does not accumulate when administered to rats.

In clinical trials, analysis of serum clobetasol levels after 4 weeks of daily application of CLOBEX Shampoo showed no detectable exposure in 97% of patients.

Indications

Topical treatment of moderate to severe scalp psoriasis.

Dosage and Administration

CLOBEX Shampoo should be applied to the dry (not wet) scalp once a day. It should be massaged gently into the lesions and left in place for 15 minutes before lathering and rinsing off. Treatment should be limited to 4 weeks. The mean amount of shampoo

usually used in clinical trials was 50g per week.

Contraindications

Hypersensitivity to any of the ingredients in the preparation.

Should not be applied to any areas of the scalp affected by viral or bacterial infections. Do not use in the eyes. Do not use on areas other than the scalp. Do not use on children under 1 year of age.

Warnings and Precautions

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur readily even without occlusion. If CLOBEX Shampoo is required for children; it is recommended that treatment should be reviewed weekly.

Contact with the eyes should be avoided as glaucoma or cataract may result. If CLOBEX Shampoo enters the eye; it should be rinsed thoroughly with copious amounts of water. The face, more than other areas of the body, may exhibit atrophic changes, telangiectasia or corticoid-induced dermatitis after prolonged treatment with potent topical corticosteroids. Patients should be warned to minimise contact with the face when rinsing off the product. Topical corticosteroids should be used with caution because of the potential for post-treatment rebound relapse, the development of tolerance (tachyphylaxis) and the possibility of local or systemic toxicity arising from prolonged or excessive use.

Appropriate anti-microbial therapy should be used whenever treating inflammatory lesions that have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of anti-microbial agents.

For external use only.

Use in Pregnancy

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to human beings has not been established, however, topical steroids should not be used extensively in pregnancy, i.e. in large amounts for long periods. There may be a very small risk of abnormal foetal development in the human foetus. Consequently, caution should be exercised when prescribing to pregnant women.

Use in Lactation

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Hence, caution should be exercised when CLOBEX Shampoo is administered to a nursing woman.

Adverse Effects

In controlled clinical trials with CLOBEX Shampoo, the total incidence of adverse events related to the product was about 7%. Most of these adverse events consisted of skin

discomfort and pruritus and were of mild or moderate severity. Clinical signs of irritation were seldom reported (0.3%). Adverse events were not affected by age, race or gender. No serious drug-related adverse events were reported during clinical trial use.

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercorticism.

Provided the weekly dosage is about or less than 50 g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes, such as thinning, striae, telangiectasia, erythema, purpura, contact dermatitis and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved. When applied to the face, potent corticosteroids can induce perioral dermatitis or worsen rosacea. There are reports of pigmentation changes, acne, pustula eruptions and hypertrichosis with topical corticosteroids.

Clobetasol propionate is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately. Exacerbation of symptoms may occur.

Interactions

Nil.

Overdosage

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the symptoms of severe adrenal suppression and hypercorticism may appear and in this situation topical steroids should be discontinued gradually. However, because of the risk of acute adrenal suppression this should be done under medical supervision.

Pharmaceutical Precautions

Store below 25°C, out of direct sunlight. Shelf-life 3 years unopened, or for 4 weeks when opened.

Medicine Classification

Prescription Medicine.

Package Quantities

The product is packaged in HDP bottles fitted with polypropylene closure, containing 60ml and 125ml of shampoo.

Further Information

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

Name and Address

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