CLOBETASOL PROPIONATE CREAM USP 0.05% w/w

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Steriderm-S Cream

COMPOSITION:
Clobetasol Propionate USP 0.05% w/w
in a cream base

CHEMISTRY:
Chemically it is described as [17-(2'-Chloroacetyl)-9-fluoro-11-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl] propionate

PHARMACOLOGICAL CATEGORY:
Corticosteroids

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

PHARMACOKINETICS:
Absorption: Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.
Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0.05% ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g clobetasol propionate cream 0.05% mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.
In a separate study, mean peak plasma concentrations of approximately 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.05% ointment.
Distribution: The use of Pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.
Metabolism: Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids.
Elimination: Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS:
Short-term treatment only of severe resistant inflammatory skin disorders such as recalcitrant eczemas unresponsive to less potent corticosteroids, Psoriasis

CONTRAINDICATIONS:
Acne; perioral dermatitis; widespread plaque psoriasis; rosacea (in adults); untreated bacterial, fungal or viral skin lesions

SIDE EFFECTS/ADVERSE EFFECTS:
For all CORTICOSTEROIDS (TOPICAL):
Rare: Adrenal suppression; Cushing's syndrome
Frequency not known
Acne; contact dermatitis; hypertrichosis; irreversible striae atrophicae; irreversible telangiectasia; mild depigmentation (may be reversible); perioral dermatitis; side-effects applicable to systemic corticosteroids may also apply if absorption occurs following topical and local use; spread and worsening of untreated infection; thinning of the skin (may be restored over a period after stopping treatment but the original structure may never return); worsening of acne; worsening of rosacea
Side-effects, further information: In order to minimize the side-effects of a topical corticosteroid, it is important to apply it thinly to affected areas only, no more frequently than twice daily, and to use the least potent formulation which is fully effective.

PRECAUTIONS AND WARNINGS:
For all CORTICOSTEROIDS (TOPICAL):
Avoid prolonged use (particularly on the face); cautions applicable to systemic corticosteroids may also apply if absorption occurs following topical and local use; dermatoses of infancy, including nappy rash (extreme caution required—treatment should be limited to 5–7 days) (in children); infection; keep away from eyes; use potent or very potent topical corticosteroids under specialist supervision (in children); use potent or very potent topical corticosteroids under specialist supervision in psoriasis (can result in rebound relapse, development of generalised pustular psoriasis, and local and systemic toxicity) (in adults)

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DRUG INTERACTIONS:
Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir and 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.

PREGNANCY AND LACTATION:
Pregnancy: There are limited data from the use of clobetasol 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. Administration of clobetasol during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. 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 the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of clobetasol during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.
If used during lactation clobetasol should not be applied to the breasts to avoid accidental ingestion by the infant.

DOSAGE AND ADMINISTRATION:
Short-term treatment only of severe resistant inflammatory skin disorders such as recalcitrant eczemas unresponsive to less potent corticosteroids, *Psoriasis*
To the skin
Child: Apply 1–2 times a day for up to 4 weeks, to be applied thinly.
Adult: Apply 1–2 times a day for up to 4 weeks, to be applied thinly, maximum 50 g of 0.05% preparation per week.

Potency: Clobetasol propionate 0.05% cream: very potent.
Topical use in children: *It is* not licensed for use in children under 1 year.
Directions for administration
For all CORTICOSTEROIDS (TOPICAL):
Topical corticosteroid preparations should be applied no more frequently than twice daily; once daily is often sufficient.
Topical corticosteroids should be spread thinly on the skin but in sufficient quantity to cover the affected areas. The length of cream or ointment expelled from a tube may be used to specify the quantity to be applied to a given area of skin. This length can be measured in terms of a *fingertip unit* (the distance from the tip of the adult index finger to the first crease). One fingertip unit (approximately 500 mg from a tube with a standard 5 mm diameter nozzle) is sufficient to cover an area that is twice that of the flat adult handprint (palm and fingers).
Mixing topical preparations on the skin should be avoided where possible; several minutes should elapse between application of different preparations.
In children: 'Wet-wrap bandaging' increases absorption into the skin, but should be initiated only by a dermatologist and application supervised by a healthcare professional trained in the technique.

OVERDOSAGE AND TREATMENT:
Symptoms: Topically applied clobetasol may be absorbed in sufficient amounts to produce systemic effects. Acute over dosage is very unlikely to occur, however, in the case of chronic over dosage or misuse the features of hypercortisolism may occur.
Management: In the event of overdose, clobetasol 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.

STORAGE CONDITIONS:
Store below 30°C. Keep away from reach of children.

PRESENTATION:
Aluminium tube of 15g

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