130 mm

120 mm

Package Insert

Quall™
Eczema Cream

Betamethasone Dipropionate Cream USP 0.05%

Composition
Betamethasone Dipropionate USP 0.64 mg
In a cream base q.s. to make 1g
Chlorocresol BP 1 mg
(Preservative)

Product Description

A white smooth cream, free from foreign matter.

Pharmacodynamics

Betamethasone Dipropionate is a topically active fluorinated corticosteroid which has anti-inflammatory, antipruritic and vasoconstrictive actions.

Pharmacokinetics

Betamethasone is absorbed through the skin in varying proportions of the applied dose depending upon the severity of the damage to the stratum corneum barrier that has resulted from the skin disease. It is probable that no more than 5% of the applied dose is absorbed; it is metabolized in the liver and excreted by the renal tract. The remainder will be washed off or deposited on clothes or dressings. Under plastic occlusion a much higher proportion will be absorbed due to the increased temperature and humidity.

Concentration effect relationship

Plasma concentration is not relevant for a topical preparation.

Metabolism

Little information is available. Betamethasone dipropionate is mainly excreted in urine. It is not known if there is any enterohepatic circulation. The main metabolic pathways are hydrolysis to Betamethasone (which is active) and oxidation.

Indication

For the relief of inflammatory manifestations of corticosteroid responsive dermatoses.

Recommended Dose

Apply minimum quantity of QUALL ECZEMA CREAM sufficient to cover completely the affected area twice daily, in the morning and at night. Massage gently into the affected area until the cream vanishes. Once resolution of the condition is obtained, maintenance therapy may require less frequent application.

Do not use occlusive dressings with QUALL ECZEMA CREAM.

Mode Of Administration

Topical

Contraindication

QUALL ECZEMA CREAM is contraindicated in patients who are hypersensitive to betamethasone dipropionate, to other corticosteroids or to any ingredient in this preparation.

Warning and Precautions

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Use of more than one corticosteroid-containing product at the same time may increase total systemic glucocorticoid exposure.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug.

If irritation develops topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for patients

Patients using topical corticosteroids should receive the following information and instructions. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

1. This medication is to be used as directed by the physician and should not be used longer than the prescribed time period. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive.
4. Patients should report any signs of local adverse reactions.
5. Other corticosteroid-containing products should not be used with Quall ECZEMA cream without first talking to your physician.

Interactions With Other Medicaments

No interactions between topically applied steroids and other drugs have been reported.

Pregnancy and Lactation

Topical administration of corticosteroids to pregnant animals can cause fetal abnormalities. While the relevance of this finding to human subjects has not been established, the drug should not be used on large areas of skin or in large amounts for prolonged periods during pregnancy. Caution should be exercised when this product is administered to nursing mothers.

Side Effects

The following local adverse reactions have been reported with the use of topical corticosteroids especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Symptoms And Treatment of Overdose

Corticosteroid applied to the skin can be absorbed in sufficient amounts to produce systemic effects such as hypothalamic-pituitary-adrenal axis suppression, manifestation of cushing's syndrome, hyperglycaemia and glucosuria. Tests which may be helpful in evaluating hypothalamic-pituitary-adrenal axis suppression include urinary free cortisol test and ACTH stimulation test. If the hypothalamic-pituitary-adrenal axis suppression is found, then the drug should be withdrawn, frequency of application reduced or a weaker steroid used. Supplemental systemic corticosteroids may be required if signs and symptoms of steroid withdrawal occurs.

Storage Condition

Store at a temperature below 30°C. Do not freeze.

Shelf Life

36 months from the date of manufacture.

Presentation

Pack of 15g. aluminium collapsible tube.

Date of Revision : Nov. 2019

Mfg.Lic No. : 28/9/96
Reg. No. : MAL11060001AZ

Importer & product registration holder :
Zulat Pharmacy Sdn Bhd, 23 & 23A,
Jalan Bandar 3, Taman Melawati, 53100
Kuala Lumpur, Malaysia.

torrent PHARMA
Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Plot No. 810, Sector III, Industrial Area,
Pithampur, District Dhar - 454 775 (M.P.) INDIA

xxxxxxxxx-5253

PRODUCT NAME :	Quall	**COUNTRY :** Malaysia	**LOCATION :** Pithampur		**Supersedes A/W No.:** ZQLEXX2-MY		
ITEM / PACK :	Insert	**NO. OF COLORS:** 1	**REMARK :**				
DESIGN STYLE :	-	**PANTONE SHADE NOS.:**	**SUBSTRATE :**				
CODE :	xxxxxxxxx-5253		**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) :	130 L x 120 W	Black C	Prepared By	**Pkg.Dev**			
ART WORK SIZE :	S/S		Reviewed By	**Pkg.Dev**			
DATE :	12-11-2019		Approved By	**Quality**			

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

Shalini
Regulatory Affairs
Zulat Pharmacy