

TRIONEX- calcipotriene cream, 0.005%
Florrax Pharmaceutical

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Calyxra

(NDC 84460-803-01)

Rx only
FOR TOPICAL DERMATOLOGIC USE ONLY.
Not for Ophthalmic, Oral or Intravaginal Use.

Calyxra DESCRIPTION

Calyxra is supplied as 2 components in a *kit*:

- 1 TUBE OF CALCIPOTRIENE CREAM 0.005%, 60g (NDC 68462-501-65)
- 30 SHEETS OF HYDROFILM TRANSPARENT DRESSING (1 BOXES OF 30 SHEETS)

INDICATION AND USAGE

Indicated for the treatment of plaque psoriasis.

DOSAGE AND ADMINISTRATION

Apply a thin layer of calcipotriene cream to the affected skin 1-2 times daily and rub in gently and completely. The safety and efficacy of calcipotriene cream have been demonstrated in patients treated for eight weeks.

Once calcipotriene has been completely rubbed in completely, apply transparent dressing to the affected area as needed as a protectant.

WARNINGS

FOR EXTERNAL USE ONLY. Avoid contact with eyes, lips or mucous membranes.

CONTRAINDICATIONS

Do not use if known hypersensitivity to any of the listed ingredients of *any* of the components included on the kit.

MANUFACTURED FOR:
Florrax Pharma

Dallas, TX

Rx Only

Calcipotriene Cream 0.005%

Rx Only

DESCRIPTION

Calcipotriene cream, 0.005% contains calcipotriene, USP, a synthetic vitamin D₃ derivative, for topical dermatological use.

Chemically, calcipotriene, USP is (5Z,7E,22E,24S)-24-cyclopropyl-9,10-secochola-5,7,10(19),22-tetraene-1 α ,3 β ,24-triol, with the empirical formula C₂₇H₄₀O₃, a molecular weight of 412.62 g/mol and the following structural formula:

Calcipotriene, USP is a white or almost white crystalline powder. Calcipotriene cream, 0.005% contains 50 mcg/g anhydrous calcipotriene, USP in a cream base of benzyl alcohol, cetostearyl alcohol, ceteth-20, cetostearyl alcohol, disodium hydrogen phosphate dihydrate, glycerin, medium chain triglycerides, mineral oil, monosodium phosphate monohydrate, purified water and white petrolatum.

CLINICAL PHARMACOLOGY

In humans, the natural supply of vitamin D depends mainly on exposure to the ultraviolet rays of the sun for conversion of 7-dehydrocholesterol to vitamin D₃ (cholecalciferol) in the skin. Calcipotriene is a synthetic analog of vitamin D₃.

Clinical studies with radiolabelled calcipotriene ointment indicate that approximately 6% (\pm 3%, SD) of the applied dose of calcipotriene is absorbed systemically when the ointment is applied topically to psoriasis plaques, or 5% (\pm 2.6%, SD) when applied to normal skin, and much of the absorbed active is converted to inactive metabolites within 24 hours of application. Systemic absorption of the cream has not been studied.

Vitamin D and its metabolites are transported in the blood, bound to specific plasma proteins. The active form of the vitamin, 1,25-dihydroxy vitamin D₃ (calcitriol), is known to be recycled via the liver and excreted in the bile. Calcipotriene metabolism following systemic uptake is rapid, and occurs via a similar pathway to the natural hormone.

CLINICAL STUDIES

Adequate and well-controlled trials of patients treated with calcipotriene cream have demonstrated improvement usually beginning after 2 weeks of therapy. This improvement continued with approximately 50% of patients showing at least marked improvement in the signs and symptoms of psoriasis after 8 weeks of therapy, but only approximately 4% showed complete clearing.

INDICATIONS AND USAGE

Calcipotriene cream, 0.005%, is indicated for the treatment of plaque psoriasis. The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established.

CONTRAINDICATIONS

Calcipotriene cream is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. It should not be used by patients with demonstrated hypercalcemia or evidence of vitamin D toxicity. Calcipotriene cream should not be used on the face.

WARNINGS

Contact dermatitis, including allergic contact dermatitis, has been observed with the use of calcipotriene cream.

ADVERSE REACTIONS

Clinical Trials Experience

In controlled clinical trials, the most frequent adverse experiences reported for calcipotriene cream, 0.005% were cases of skin irritation, which occurred in approximately 10 to 15% of patients. Rash, pruritus, dermatitis and worsening of psoriasis were reported in 1 to 10% of patients.

Postmarketing Experience

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions associated with the use of calcipotriene cream have been identified post-approval: contact dermatitis, including allergic contact dermatitis.

OVERDOSAGE

Topically applied calcipotriene can be absorbed in sufficient amounts to produce systemic effects. Elevated serum calcium has been observed with excessive use of topical calcipotriene. If elevation in serum calcium should occur, discontinue treatment until normal calcium levels are restored (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

Apply a thin layer of calcipotriene cream to the affected skin twice daily and rub in gently and completely. The safety and efficacy of calcipotriene cream have been demonstrated in patients treated for eight weeks.

HOW SUPPLIED

Calcipotriene cream, 0.005% is available in:

NDC 68462-501-65 60 gram tube (1 tube per carton)

STORAGE

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Do not freeze.

Manufactured by:

Glenmark Pharmaceuticals Limited

Colvale-Bardez, Goa 403513, India

Manufactured for:



Glenmark Pharmaceuticals Inc., USA

Mahwah, NJ 07430

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

To report SUSPECTED ADVERSE REACTIONS, contact Glenmark

Pharmaceuticals Inc., USA at 1 (888) 721-7115 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

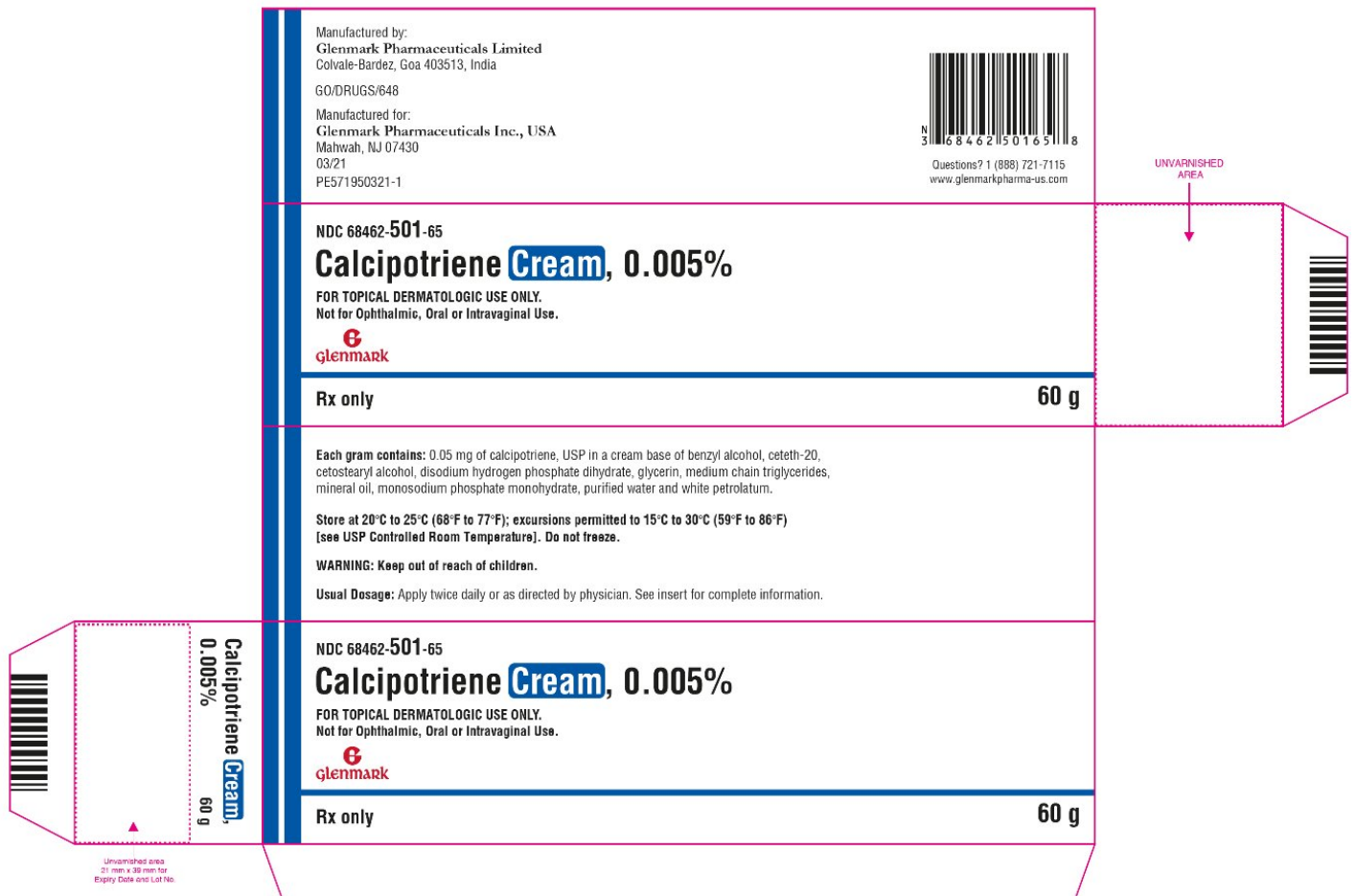
March 2021

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL-60 gm Carton

NDC 68462-501-65

Calcipotriene Cream, 0.005%

60 gm Carton label



Hydrofilm Transparent Dressing

30 Sheets of Hydrofilm transparent sterile dressing that contains a transparent, semi-permeable polyurethane polyacrylate top layer and hypoallergenic, polyacrylate adhesive layer. The dressing is used to protect against secondary infection and against mechanical irritation of wounds in later stages of healing.

PRINCIPAL DISPLAY PANEL - Kit Carton

Florrax Pharma

Calyxra

NDC 84460-803-01 RX ONLY



pdp

TRIONEX

calcipotriene cream, 0.005% kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84460-803
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84460-803-01	1 in 1 KIT; Type 0: Not a Combination Product	03/24/2026	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	60 g
Part 2	3 BOX	30

Part 1 of 2

CALCIPOTRIENE

calcipotriene cream

Product Information

Item Code (Source)	NDC:68462-501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIPOTRIENE (UNII: 143NQ3779B) (CALCIPOTRIENE - UNII:143NQ3779B)	CALCIPOTRIENE	50 ug in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
water (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68462-501-65	1 in 1 CARTON		
1		60 g in 1 TUBE; Type 0: Not a Combination		

Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205772	06/10/2015	

Part 2 of 2

HYDROFILM

dressing, wound, occlusive

Product Information

Item Code (Source)	GS1:4049500630955
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 in 1 BOX; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Exempt device	ABC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/13/2023	

Labeler - Florrax Pharmaceutical (119257612)