

# Prescribing Information

## Pf TOPACTIN CREAM 0.05%

DIN: 00816132

### *0.05% Fluocinonide cream USP*

#### ***DESCRIPTION***

TOPACTIN CREAM (fluocinonide 0.05%) are anti-inflammatory, anti-pruritic and vaso-constrictor agents for topical use in the management of corticosteroid responsive dermatoses. TOPACTIN contains fluocinonide (21-(acetyloxy) 6 alpha , 9-difluoro-11beta -hydroxy-16alpha , 17-[(1-menthylethylidene) bis (oxy)] pregna-1, 4-diene-3,20-dione.) in bases formulated for optimal release of the active ingredient. In these formulations, the active ingredient is totally in solution and the formulation contains no lanolin or parabens known to be potential sensitizers.

Topactin cream contains: Stearyl alcohol, Mineral oil, Steareth 21, Brij 72, Dichlorobenzyl alcohol, EDTA disodium, Germall II (*preservative*).

#### ***INDICATIONS***

Topactin is intended for topical use in the management of acute or chronic corticosteroid responsive dermatoses such as psoriasis, atopic dermatitis, seborrheic dermatitis, contact dermatitis, eczematous dermatitis, lichen planus, neurodermatitis, intertriginous psoriasis, nummular eczema, exfoliative dermatitis, pruritus ani and pruritus vulvae, lichen simplex chronicus, intertrigo, post-anal surgery, otitis, externa and stasis dermatitis. TOPACTIN CREAM is recommended for moist, weeping lesions.

#### ***CONTRAINDICATIONS***

Topical corticosteroids are contraindicated in tuberculous fungal and most viral lesions of the skin (including herpes simplex, vaccinia and varicella), and also contraindicated in individuals with a history of hypersensitivity to their components. THIS PREPARATION IS NOT FOR OPHTHALMIC USE.

## ***PRECAUTIONS***

Although side effects are not ordinarily encountered with topically applied corticosteroids, as with all drugs a few patients may react unfavorably under certain conditions. Should sensitivity or idiosyncratic reaction occur, the drug agent should be discontinued and appropriate steps taken. In the presence of an infection, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid cream should be discontinued until the infection has been adequately controlled. It is recommended that TOPACTIN not be used under occlusive dressings since the efficacy and safety of TOPACTIN under occlusive dressings has not yet been established.

Although topical steroids have not been reported to have an adverse effect on pregnancy, the safety of their use in pregnant females has not been established. Therefore, they should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time. Patients should be advised to inform subsequent physicians of the prior use of corticosteroids. Causal factors should be eliminated whenever possible. It is recommended that rotation of sites of application and intermittent therapy should be considered.

## ***ADVERSE REACTIONS***

Side effects have been extremely rare and consist mainly of local burning, irritation and itching. When this occurs, the possibility of sensitization must be kept in mind. However, TOPACTIN does not contain lanolin, parabens or phenolic compounds which have been recognized as potential sensitizers. Because skin atrophy, striae, hypertrichosis and adrenal suppression have been shown to occur with prolonged and indiscriminate use of topical corticosteroids, particularly under occlusion, due to percutaneous absorption, similar phenomena could conceivably occur with prolonged and excessive use of TOPACTIN. Posterior subcapsular cataracts have been reported following the systemic use of corticosteroids.

## ***DOSAGE***

TOPACTIN CREAM (fluocinonide 0.05%) – A small amount should be applied to the affected skin area two to four times daily as needed and massaged gently but thoroughly until it disappears.

## ***AVAILABILITY***

- Topactin Cream 0.05% Metal tube: 60g
- Topactin Cream 0.05% HDPE Jar: 450g

**Triton Pharma Inc.**  
**665 Millway Avenue, Unit 31B**  
**Concord, Ontario**  
**L4K 3T8**

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