PRESCRIBING INFORMATION

TIAMOL®
(Fluocinonide Cream, USP) Emollient Base

Topical Corticosteroid

TaroPharma, A Division of Taro Pharmaceuticals Inc.
130 East Drive
Brampton, Ontario, Canada
L6T 1C1

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Topical Corticosteroid

PHARMACOLOGY
Fluocinonide is effective because of the anti-inflammatory, antipruritic and vasoconstrictor actions of fluocinonide.

INDICATIONS
For topical use in the management of acute or chronic dermatoses responsive to corticosteroids.

CONTRAINDICATIONS
Topical corticosteroids are contraindicated in tuberculosis, fungal, most viral lesions of the skin (including herpes simplex, vaccinia and varicella), untreated bacterial infections and also contraindicated in individuals with a history of hypersensitivity to its components. This preparation is not for ophthalmic use.

WARNINGS
Adrenal suppression and other systemic effects may occur after applications to extensive areas and prolonged usage. Fluocinonide should not be used under occlusive dressings. Not for ophthalmic use.

Dilution of a physical topical, commercially formulated corticosteroid preparation may result in a physical incompatibility or an unstability of the active ingredients. Manipulation of the preparation may cause bacterial contamination or alter the release of active ingredients from the base.

Pregnancy and Lactation*:* The safety of topical corticosteroid preparations during pregnancy and lactation has not been established; therefore, they should not be used on pregnant patients.

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 symptoms of hypersensitivity or idiosyncrasy occur, the medication should be discontinued and appropriate steps taken.

If the lesion is infected 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.

If extensive areas are treated, the -possibility exists of increased systemic absorption requiring that the amount applied and frequency of application be suitably adjusted.

Patients should be advised to inform other physicians attending them of their use of corticosteroids.

Causal factors of dermatoses should be eliminated whenever possible.

It is recommended that rotation of sites of application and intermittent therapy should be considered.

Application in or near the eye should be avoided.

Prolonged use of topical corticosteroid products may produce atrophy of the skin and of subcutaneous tissues, particularly on flexor surfaces and on the face. If this is noted, discontinue the use of this product.

Fluocinonide should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation.

During the use of topical corticosteroids secondary infections may occur.

ADVERSE EFFECTS

The following adverse skin reactions have been reported with the use of topical steroids: dryness, itching, burning, local irritation, striae, skin atrophy, atrophy of the subcutaneous tissues, telangiectasia, hypertrichosis, change in the pigmentation and secondary infection.

Adrenal suppression has also been reported following topical corticosteroid therapy.

Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

DOSAGE

Suitable when an emollient effect is desired. A small amount is applied lightly to affected skin area 2 to 4 times daily with gentle but thorough massage.

HOW SUPPLIED

Each gram of cream contains: fluocinonide 0.05% in an emollient base.
Nonmedicinal ingredients: cetyl alcohol, citric acid, mineral oil, polysorbate-60, propylene glycol, sorbitan monostearate, stearyl alcohol and white petrolatum. Jars of 100g. Tubes of 25g.