

MOMOZ T

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **MOMOZ T** (Mometasone Furoate with Terbinafine Hydrochloride Cream)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Mometasone Furoate:* Like other topical corticosteroids, Mometasone furoate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2. *Terbinafine Hydrochloride:* Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane. The enzyme squalene epoxidase is not linked to the cytochrome P-450 system. Terbinafine does not influence the metabolism of hormones or other drugs.

INDICATIONS: For the treatment of Topical fungal infection associated with inflammation & pruritis.

DOSAGE AND ADMINISTRATION: As directed by Physician. For external use only.

CONTRAINDICATION: Hypersensitivity to the active substances Terbinafine Hydrochloride, Mometasone Furoate or to other corticosteroids or to any of the excipients. In facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyoderma), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post vaccine reactions. On wounds or on skin which is ulcerated. MOMOZ T should not be used in patients who are sensitive to Mometasone Furoate or to any of the excipients.

WARNINGS & PRECAUTIONS: *Mometasone Furoate:* If irritation or sensitisation develop with the use of Momoz F, treatment should be withdrawn and appropriate therapy instituted. Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled. Systemic absorption of topical corticosteroids can produce reversible hypothalamic pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glycosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. As the safety and efficacy of Mometasone Furoate in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended. Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age. Topical steroids may be hazardous in psoriasis for a number

of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment. Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing. Mometasone Furoate topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract. Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient present with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Terbinafine Hydrochloride: Terbinafine may be irritating to the eyes. Contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse eyes thoroughly with running water. Momoz T cream should be kept out of the reach of children. In the event of allergic reaction, the cream should be removed and the treatment interrupted. Candidiasis: It is not recommended to use acid pH soap. This provides favourable growth conditions for *Candida* spp. Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipients

This medicine contains benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation. This medicine also contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)..

DRUG INTERACTIONS: No drug interactions are known with the topical forms of terbinafine and/or mometasone.

ADVERSE REACTIONS: *Mometasone Furoate:* Infection, furuncle, Folliculitis, Paraesthesia, Burning sensation, Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy, Pruritus, Application site pain, application site reactions, Vision blurred. *Terbinafine Hydrochloride:* Hypersensitivity, Eye irritation, Skin exfoliation, pruritus, Skin lesion, scab, skin disorder, pigmentation disorder, erythema, skin burning sensation, Dry skin, dermatitis contact, eczema, Rash, Acute generalised Exanthematous pustulosis (AGEP), Pain, application site pain, application site irritation, Condition aggravated

MARKETED BY:



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IN/ MOMOZ T 1 and 0.1 %w/w /APR-20/01/ABPI

(Additional information is available on request)