MOMOZ S

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

Abbreviated Prescribing information for **MOMOZ S** (Mometasone Furoate 0.1% & Salicylic Acid 5% Ointment)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Mometasone Furoate:* Mometasone Furoate exhibits marked anti-inflammatory activity and marked antipsoriatic activity in standard animal predictive models. *Salicylic acid:* Salicylic acid is keratolytic by lowering the pH of the skin, resulting in increased hydration of the keratin and swelling of the corneocytes. It also solubilizes the intercellular cement substance in the stratum corneum, facilitating desquamation. Salicylic acid does not change the mitotic rate of the basal keratinocytes. It is mildly antipruritic and anti-inflammatory

INDICATIONS: It is indicated for the treatment of plaque Psoriasis.

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

CONTRAINDICATION: Contraindicated in patients displaying salicylate hypersensitivity, Mometasone Furoate or sensitivity to any other ingredient in the preparation**.** It is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), 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. MOMOZ S should not be used on wounds or on skin which is ulcerated. MOMOZ S should not be used in patients who are sensitive to Salicylic Acid, Mometasone Furoate, or to other corticosteroids or to any of the excipients.

WARNINGS & PRECAUTIONS: If irritation or sensitisation develop with the use of Momoz S, treatment should be withdrawn and appropriate therapy instituted.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. For external use only.Avoid contact with broken or inflamed skin. Salicylate toxicity may occur if applied to large areas of skin or to the skin of neonates.

DRUG INTERACTIONS: There are no known interactions when used as indicated. However, topical salicylic acid may increase the absorption of other topically applied medicines. Concomitant MOMOZ S and other topical medicines on the same area of skin should therefore be avoided.

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. Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, malaria and telangiectasia. Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid induced hypothalamic pituitary adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Chronic corticosteroids therapy may interfere with the growth and development of children. Possible sensitivity reactions, drying and irritation.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ MOMOZ S 0.1% w/w, 5.0% w/w /AUG-20/01/ABPI
(Additional information is available on request)