

MELOMET LOTION 0.1% W/W

Ingredient(s):

Each gram contains:

Mometasone Furoate 1mg

Pharmacodynamics:

Mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

Pharmacotherapeutic group: Mometasone

Pharmacokinetics:

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate 0.1% ointment is minimal, approximately 0.7% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta. Minimal absorption would be anticipated with the lotion formulation.

Indication:

Indicated for the relief of the inflammatory and pruritic manifestation of corticosteroid responsive dermatoses. The lotion formulation may be applied to scalp lesions.

Recommended Dosage:

Apply a few drops of Melomet Lotion 0.1% w/w to affected skin areas including scalp sites once daily; massage gently and thoroughly until the medication disappears.

Route of Administration:

Topical application.

Contraindications:

Melomet Lotion 0.1% w/w is contraindicated in skin atrophy, 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 of the scalp. Melomet Lotion 0.1% w/w should not be used on wounds or on skin which is ulcerated. Melomet Lotion 0.1% w/w should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the excipients.

Warnings and Precautions:

If irritation or sensitisation develop with the use of Melomet Lotion 0.1% w/w, treatment should be withdrawn and appropriate therapy instituted.

Should an infection develop, use of an appropriate antifungal or antibacterial agent could 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, hyperglycaemia, 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 Melomet Lotion 0.1% w/w 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. If used in childhood, occlusion should not be used and courses should be limited to 5 days. 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 patient, careful 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.

Melomet Lotion 0.1% w/w contains propylene glycol which may cause skin irritation. Care must be taken to keep the preparation away from the eyes. Melomet 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 presents 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.

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.

Interactions with Other Medicaments:

Not known.

Pregnancy and Lactation:

During pregnancy treatment with Melomet Lotion 0.1% w/w should be performed only on the physician's order. Then however, the application on large body surface areas or over a prolonged period should be avoided. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation.

There are no adequate and well-controlled studies with Melomet Lotion 0.1% w/w in pregnant women and therefore the risk of such effects to the human foetus is unknown. However as with all topically applied glucocorticoids, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. There may therefore be a very small risk of such effects in the human foetus. Like other topically applied glucocorticoids, Melomet Lotion 0.1% w/w should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Melomet Lotion 0.1% w/w should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. If treatment with higher doses or long term application is indicated, breast-feeding should be discontinued.

Side Effects:

Local adverse reactions rarely reported include burning, folliculitis, acneiform reaction, pruritus and signs of skin atrophy. The following local adverse reactions have been reported infrequently with the use of other topical corticosteroids: irritation, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria. Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

Overdose and Treatment:

Symptoms: Excessive, prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

Storage Conditions:

Keep in an airtight container.

Store at temperature below 30°C

Protect from light and moisture.

Product Description and Packaging:

Clear and colorless lotion, slightly viscous solution.

HDPE Plastic bottle 30ml & 75ml.



Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor, Malaysia.
Ordering Line: 1 800 88 3027
Product Info: 1 800 88 3679