MELOMET CREAM 0.1%

Ingredient(s):
Each gram contains:
Mometasone Furoate 1mg

Preservative(s):
Each gram contains:
Methyl Paraben 2mg
Propyl Paraben 0.5mg

Excipients:
Propylene Glycol, Stearic Acid, Cetearyl-6 and Stearyl Alcohol, Propylparaben, Titanium Dioxide, Cetearyl Alcohol and Sodium Lauryl Sulphate, White Petrolatum, Mineral Oil, Methylparaben, Potassium Phosphate Monobasic, Phosphoric Acid and Purified Water

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetics):
Mometasone furoate, a synthetic corticosteroid, exhibits marked anti-inflammatory, antipruritic and vasoconstrictive properties. Although the mechanism of anti-inflammatory activity is generally unclear, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostagladins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate cream 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterization of metabolites is not possible owing to the small amounts present in plasma and excreta.

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(±2mm)

Indication(s):
Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Dosage and Administration:
Apply a thin film to the affected skin areas once daily until the lesion heals or for a duration of 3 weeks whichever is sooner.

Contraindication(s):
Contraindicated in those patients with a history of hypersensitivity to mometasone furoate, other corticosteroids or any of the components in the preparation.

Precaution(s) / Warning(s):
1. Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.
2. If irritation or sensitization develops with the use of Melomet cream, treatment should be withdrawn and appropriate therapy instituted.
3. Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.
4. Local and systemic toxicity is common especially following long continued use on large areas of damaged skin. Long term continuous therapy should be avoided in all patients irrespective of age.
5. Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used.
6. Melomet cream is not for ophthalmic use.
7. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth and development of children.

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8. Visual disturbance may be reported with systemic and topical 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 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.

Pregnancy and Lactation:
Use in pregnancy:
There is inadequate evidence to support the safe use 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 may therefore be a very small risk of such effects in the human foetus. It should be used during pregnancy only if the potential benefit justifies potential risk to the fetus. Drugs of this class should not be used on pregnant patients in large amounts or for prolonged periods of time.

Use in lactation:
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Side Effect(s) / Adverse Reaction(s):
1. Local adverse reactions reported very rarely include paresthesia, pruritus and signs of skin atrophy.
2. Local adverse reactions reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings include irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of skin, secondary infection, striae, and miliaria.
3. Eye disorders: Vision, blurred.

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Symptoms and Treatment for Overdosage, and Antidote(s):
Excessive, prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency.
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.

Shelf-Life:
3 years from the date of manufacture.

Storage Condition(s):
Keep in an airtight container. Store at temperature below 30°C. Protect from light and moisture.

Product Description & Packing(s):
A white coloured cream.
Aluminium tube of 5g, 10g, 20g & 45g
HDPE plastic jar of 500g.

(Not all presentations may be available locally)

Y. S. P.®

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
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