Prescribing Information (Summary of Product Characteristics)

1. Name of the medicinal product

Trade name : MFSONE CREAM
Generic name : Mometasone Furoate Cream USP 0.1% w/w

2. Qualitative and Quantitative composition

Qualitative Composition
Mometasone Furoate USP .....0.1 % w/w
In a cream base .....q.s.
For external use only

Quantitative composition
Excipients with known effect
40 mg of Propylene Glycol (Cosolvent), 1.8 mg of Methyl Paraben (Antimicrobial agent), 0.2 mg of Propyl Paraben (Antimicrobial agent), 80 mg of Light Liquid Paraffin (Emollient; oleaginous vehicle) / 1 gm.

For full list of excipients see section 6.1

3. Pharmaceutical form

Prescription Only Medicine

Semi solid dosage form (cream)
White homogenous semi-solid mass filled in printed lami tubes

4. Clinical Particulars

1. Therapeutic indications

Mometasone Furoate 1mg/g Cream is indicated for the treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopicdermatitis. This medicinal product is indicated in adults and children above 6 years of age.

2. Posology and method of administration

Posology

Adults, including elderly patients, adolescents and children aged 6 years and over:

A thin film of Mometasone Furoate 1mg/g Cream should be applied to the affected areas of skin once daily. One fingertip unit (a line from the tip of an adult index fingerto the first crease) is enough to cover an area twice the size of an adult hand. Use of a weaker corticosteroid is often advisable when there is a clinicalimprovement.

Paediatric population

Mometasone Furoate 1mg/g Cream should not be used for long periods (over 3 weeks) or on large areas (over 20% of body surface area). In children a maximum of 10% of body surface area should be treated.

Use of topical corticosteroids in children aged 6 years and over, or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

3. Contraindications

Mometasone Furoate 1mg/g Cream 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, chickenpox, verrucae vulgares, condylomata acuminate and molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions. Mometasone Furoate 1mg/g Cream should not be used on wounds or on skin which is ulcerated.

4. Special warnings and precautions for use

If irritation or sensitisation develop with the use of Mometasone Furoate 1mg/g Cream, 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-pituitaryadrenal (HPA) axis suppression with the potential for glucocorticosteroid in- sufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycaemia, and glucosuria can also be produced in some patients by systemic ab- sorption 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 dosesdue to their larger skin surface to body mass ratios. As the safety and efficacy of Mometasone Furoate in paediatric patients below 6 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 re- bound 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 in-stance 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 1mg/g Cream contains propylene glycol which may cause skin irritation. Mometasone Furoate 1mg/g Cream contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Mometasone Furoate 1mg/g Cream topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

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

Precautionary Statements:
"MFSONE contains Propylene glycol which may cause skin irritation and also MethylParaben and Propyl Paraben, which may cause allergic reactions (Possibly delayed)."

5. Interaction with other medicinal products and other forms of interaction
None stated.

6. Fertility, pregnancy and lactation
Pregnancy
During pregnancy and lactation treatment with Mometasone Furoate 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 fetal development including cleft palate and intra-uterine growth retardation. There are no adequate and well-controlled studies with Mometasone Furoate in pregnant women and therefore the risk of such effects to the human fetus is unknown. However as with all topically applied glucocorticoids, the possibility that fetal 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 fetus. Like other topically applied glucocorticoids, Mometasone Furoate should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the fetus.

Breast-feeding
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Mometasone Furoate 1mg/g Cream 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.

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7. Effects on ability to drive and use machines
None stated.

8. Undesirable effects
Treatment related adverse reactions reported with Mometasone Furoate by body system and frequency

Very common $(\geq 1/10)$; very common $(\geq 1/100,$ <1/10); uncommon <1/100); $(\geq 1/1,000,$ rare $(\geq 1/10,000,$ <1/1,000);
rare (<1/10 000,); not known(cannot be estimated from available data)

Infections and infestations Not knownVery rare	Infection, furuncleFolliculitis
Nervous system disorders Not knownVery rare	Paraesthesia, Burning sensation
Eye disorders Not known	Vision blurred
Skin and subcutaneous tissue disorders Not known	Dermatitis contact, skin hypopigmentation, hyper-trichosis, skin striae, dermatitis acneiform, skin

Very rare **General disorders and administration site conditions** Not known	atrophy Pruritus Application site pain, application site reactions

Local adverse reactions reported infrequently with topical dermatalogic 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 thanmature patients because of a larger skin surface area to body weight ratio.

Chronic corticosteroids therapy may interfere with the growth and development of children.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the TMDA ADR reporting tool; Website: www.tmda.go.tz or search for TMDA Adverse Reaction Reporting Tool in the Google play Store.

9. Overdose
Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency which is usuallyreversible. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application or to substitute a less potent steroid. The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. Pharmacological properties

1. Pharmacodynamic Properties

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

In the croton oil assay in mice, mometasone was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications.

In guinea pigs, mometasone was approximately twice as potent as betamethasone valerate in reducing m. ovalis induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications.

2. Pharmacokinetic properties

Pharmacokinetic studies have indicated that systemic absorption following topical application of Mometasone Furoate cream 1mg/g 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 was not feasible owing to the small amountspresent in plasma and excreta.

3. Preclinical safety data

There are no findings of relevance to the prescriber other than those mentioned elsewhere in the SmPC.

6. Pharmaceutical particulars

1. List of Excipients

Edetate Disodium, Propylene Glycol, Methyl Paraben, Propyl Paraben, Light Liquid Paraffin, Isopropyl Alcohol, Acrypol (Carbomer)-940, Stearic Acid, Polysorbate-20, Emulsifying Wax (Cresmer EW), Glyceryl Mono Stearate, Cetyl Alcohol, Perfume Lavender Aroma, Purified water.

2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

3. Shelf Life

24 months form the date of manufacturing

Cream should be used within 3 months after opening the tube when stored in the same proposed storage conditions.

4. Special Precautions for Storage
Do not store above 30°C. Protect from light and moisture. Do not refrigerate or freeze.

5. Nature and Contents of container
Pack 15 g soft mass in printed lami tube, with mono carton & printed insert.

6. Instructions for user handling
Carefully read the instructions before use. Consult your doctor for further information.

7. Marketing Authorization Holder
KLM Laboratories Pvt Limited
1004, Hubtown Viva, Western Express Highway.
Jogeshwari (E), Mumbai-400060, India.

Manufactured by
East African (India) Overseas
Plot. No. 1, Pharmacity, Selaqui,
Dehradun-248011, Uttarakhand, India.

8. Marketing Authorization Number
TAN 22 HM 0023

9. Date of First Authorization/Renewal of Authorization
10/01/2022

10. Date of Revision of the Text