

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

## 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

- 1.1 Brand Name : **Momson Cream**  
1.2 Generic Name : **Mometasone Furoate Cream USP**  
1.3 Strength : **0.1%w/w**  
1.4 Pharmaceutical Form: **Topical Cream**

## 2. QUALITATIVE & QUANTITATIVE COMPOSITION :

|                       |     |            |
|-----------------------|-----|------------|
| Mometasone Furoate    | USP | 0.1 % w/w  |
| Cream Base            |     | q.s.       |
| <b>Preservatives:</b> |     |            |
| Methyl Paraben        | USP | 0.2 % w/w  |
| Propyl Paraben        | USP | 0.02 % w/w |

## 3. PHARMACEUTICAL FORM

Topical Cream

White coloured smooth perfumed cream.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

**Momson Cream** (Mometasone Furoate) is a medium potency corticosteroid indicated for the relief of severe inflammatory skin disorders such as eczemas unresponsive to less potent corticosteroids; psoriasis and pruritic manifestations of corticosteroid-responsive dermatoses.

### 4.2 Posology and method of administration

Puncture the tube nozzle before use. Apply a thin film gently to the affected areas. The usual frequency of application is twice daily in the morning and at night or as directed by physician. Use of topical corticosteroids in children or on the face should be limited to the least amount comparable with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

### 4.3 Contraindications

Mometasone Furoate 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 acuminata 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. Mometasone Furoate should not be used in patients who are sensitive to Mometasone Furoate or other excipients.

### 4.4 Special warnings and special precautions for use

Avoid prolonged use of a topical corticosteroid on the face (and keep away from eyes). In children avoid prolonged use and use potent or very potent corticosteroids under specialist supervision; extreme caution is required in dermatoses of infancy including nappy rash-treatment should be limited to 5-7 days. It may be used in paediatric patients 2 years of age or older. Psoriasis: The use of potent or very potent corticosteroids in psoriasis can result in

rebound relapse, development of generalized pustular psoriasis and local and systemic toxicity. Therefore it should be avoided or given only under specialist supervision in psoriasis. Mometasone Furoate Cream should not be used with occlusive dressings unless directed by a physician. It should not be applied in the diaper area if the child still requires diapers or plastic pants, as these garments may constitute occlusive dressing. Mometasone Furoate Cream is for topical use only. Avoid use on the face, groin, or axillae. It is not for oral, ophthalmic, or intravaginal use. If irritation or sensitisation develop with the use of Mometasone Furoate 0.1% w/w Cream, treatment should be withdrawn and appropriate therapy instituted.

#### **4.5 Interaction with other FPPs and Other forms of Interaction**

The keratolytic effect of salicylic acid facilitates the absorption of topical corticosteroids; however, excessive and prolonged use of topical preparation containing salicylic acid may cause salicylism.

#### **4.6 Pregnancy and lactation**

There are no adequate and well-controlled studies in pregnant women. Therefore, Mometasone Furoate Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk because many drugs are excreted in human milk, caution should be exercised when Mometasone Furoate Cream is applied to a nursing woman.

#### **4.7 Effects on ability to drive and use machines**

Not Known

#### **4.8 Undesirable effects**

Mild & moderately potent topical corticosteroids are associated with few side effects but care is required in the use of potent & very potent corticosteroids. Absorption through the skin can rarely cause adrenal suppression and even Cushing's syndrome, depending on the area of the body being treated and the duration of treatment. Absorption is greatest where the skin is thin or raw, and from intertriginous areas; it is increased by occlusion.

**Local side effects include:** Spread and worsening of untreated infection; thinning of the skin which may be restored over a period after stopping treatment but the original structure may never return; irreversible striae atrophicae and telangiectasia; contact dermatitis; perioral dermatitis; acne, or worsening of acne or rosacea; mild depigmentation which may be reversible; hypertrichosis also reported. In order to minimize the side-effects of topical corticosteroids, it is important to apply it thinly to affected areas only, no more frequently than twice daily, and to use the least potent formulation which is fully effective.

**Adverse Reaction:** The adverse reactions were reported to be possible or probably related to treatment with Mometasone Furoate Cream are burning, furunculosis, pruritus, skin atrophy, tingling/stinging, folliculitis, moniliasis, paraesthesia, skin depigmentation, rosacea & cataract.

#### **4.9 Overdose**

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

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**

#### **5.1 Pharmacodynamic properties:**

**Pharmacotherapeutic group:** Anti-inflammatory.

**ATC Code: D07AC13**

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.

**5.2 Pharmacokinetic properties**

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Studies in humans indicate that approximately 0.4% of the applied dose of Mometasone Furoate Cream enters the circulation after 8 hours of contact on normal skin without occlusion. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

**5.3 Preclinical safety data**

None Known

**6. PHARMACEUTICAL PARTICULARS****6.1 List of excipients**

| SN  | Ingredients                                       | Spec. |
|-----|---|-------|
| 01. | Methyl Hydroxybenzoate<br>(Methylparaben)         | USP   |
| 02. | Propyl Hydroxybenzoate<br>(Propylparaben)         | USP   |
| 03. | Macrogol Cetostearyl Ether<br>(Cetomacrogol-1000) | BP    |
| 04. | Cetostearyl Alcohol                               | BP    |
| 05. | Liquid Paraffin(H)                                | BP    |
| 06. | Propylene Glycol                                  | BP    |
| 07. | White Soft Paraffin<br>(White Petroleum Jelly)    | BP    |
| 08. | Sodium phosphate                                  | BP    |
| 09. | Phosphoric Acid                                   | BP    |
| 10. | Perfume Spring Awakening<br>(P-4200)              | IH    |
| 11. | Purified Water                                    | BP    |

**6.2 Incompatibilities**

Not sufficient data available

**6.3 Shelf life**

24 month from the date of manufacturing.

**6.4 Special precautions for storage**

Do not Freeze. Protect from light. Keep Out of reach of Children. Store at a temperature not exceeding 30°C

**6.5 Nature and contents of container**

15 g. in an aluminium lacquered collapsible tube in an inner carton.

**6.6 Instructions for use and handling**

Please see the package insert.

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS**

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**8. MARKETING AUTHORISATION NUMBER**

**07435/08847/NMR/2021**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**Oct 1, 2022.**

**10. DATE OF REVISION OF THE TEXT**

**01/01/2023**