SUMMARY OF PRODUCT CHARACTERISTICS

1.	**Name of the Medical Product**
	1.1 Product Name : MOMADERM (Mometasone Furoate Cream USP 0.1% w/w)
	1.2 Strength : Each gram contains: Mometasone Furoate USP ---------- 1 mg Cream Base…….…… q.s.
	1.3 Pharmaceutical Dosage Form : Cream (Semi Solid)
2.	**Qualitative & Quantitative Composition:** MOMADERM (Mometasone Furoate Cream USP 0.1% w/w) Each gram contains: Mometasone Furoate USP ---------- 1 mg Cream Base…….…… q.s. For a full list of excipients, see section 6.1 of SmPC
3.	**Pharmaceutical Form:**
	Cream (Semi Solid) MOMADERM (Mometasone Furoate Cream USP 0.1% w/w) : White coloured, smooth, homogenous cream.
4.	**Clinical Particulars**
	4.1 Therapeutic Indications: Mometasone furoate Cream is indicated for the treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis.
	4.2 Posology and Method of administration: Adults, including elderly patients and Children: A thin film of Mometasone furoate Cream should be applied to the affected areas of skin once daily. Use of topical corticosteroids in children 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.
	4.3 Contraindications: Mometasone furoate is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritus, 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. Mometasone furoate 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 to other corticosteroids or to any of the excipients.
	4.4 Special warning and precautions for use: If irritation or sensitisation develop with the use of Mometasone furoate, treatment should be withdrawn and appropriate therapy instituted.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. 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.
	4.5 Interactions with other medicinal products and other forms of Interactions : None stated.
	4.6 Pregnancy and Lactation: <u>Pregnancy</u> During pregnancy 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 foetal 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 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, Mometasone furoate should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus. <u>Lactation</u> It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Mometasone furoate 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.

4.7 Effects on ability to drive and use machine:
None stated.

4.8 Undesirable Effects:

Table 1: Treatment-related adverse reactions reported with Mometasone furoate by body system and frequency
Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10 000,); not known (cannot be estimated from available data)

Infections and infestations	Infection, furuncle
Not known	Folliculitis
Very rare	
Nervous system disorders	Paraesthesia,
Not known	Burning sensation
Very rare	
Skin and subcutaneous tissue disorders	Dermatitis contact, skin
Not known	hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy
Very rare	Pruritus
General disorders and administration site conditions	Application site pain, application site
Not known	reactions
Eye disorders	
Not Known	Vision blurred

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasia.
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.

4.9 Overdosage:
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: Mometasone

	ATC code: D07AC13 **Mechanism of Action** 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 Pharmacokinetics Properties: 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. Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.
	5.3 Preclinical Safety data: There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.
6.	**Pharmaceutical particulars**
	6.1 List of Excipients: **MOMADERM (Mometasone Furoate Cream USP 0.1% w/w)** Cetomacrogol 1000-PA-(SG) Cetostearyl Alcohol Light Liquid Paraffin Propylene Glycol Benzyl Alcohol Sodium Thiosulphate Disodium Edetate Citric acid monohydrate Purified water
	6.2 Incompatibilities: Not Applicable
	6.3 Shelf life: 36 months
	6.4 Special Precautions for storage: Store at a temperature below 30°C. Protect from light. Do not freeze.
	6.5 Nature and contents of container: Available in a 15g aluminium collapsible tube in a carton along with pack insert.
	6.6 Special precautions for disposal: Not applicable
7.	**Marketing Authorization Holder:** Ajanta Pharma Limited

	Ajanta House, Charkop, Kandivli (West), Mumbai- 400 067, India **Manufacturing Site Address:** Ajanta Pharma Limited Mirza-Palashbari Road, Vill-Kokjhar, Kamrup (R), Guwahati, Assam-781128. India.
8.	**Marketing Authorization Numbers:** Not applicable
9.	**Date of first registration /renewal of the registration:** Not Applicable
10.	**Date of revision of text:** January 27, 2021