Summary Product Characteristics (SPC)

1. Name of the medicinal product

Mometasone Ointment

2. Qualitative and quantitative composition

1 g of ointment contains 1 mg of mometasone furoate (0.1% w/w mometasone furoate).

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Is indicated for the relief of inflammatory manifestations of psoriasis and corticosteroids-responsive dermatoses.
Is indicated for the treatment of inflammatory and pruritic manifestation of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis

4.2 Posology and method of administration

Adults, including elderly patients, adolescents and children:
A thin film of Mometasone Ointment 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
Children below 2 years:
Not recommended
Duration of treatment should be not more than 5 days

4.3 Contraindications

Hypersensitivity to any of the ingredients
Viral infections such as herpes simplex, vaccinia and varicella
Untreated fungal infections

4.4 Special warnings and precautions for use

If irritation or sensitisation develop with the use of Mometasone, treatment should be withdrawn and appropriate therapy instituted.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 corticosteriods can produce reversible hypothalamic-pituitaryadrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria 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.
Pediatric 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 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 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 0.1% w/w Ointment contains propylene glycol which may cause skin irritation.
Mometasone Furoate 0.1% w/w Ointment topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

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

4.6 Fertility, pregnancy and lactation
Pregnancy
During pregnancy, treatment with Mometasone 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.
Should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus
Lactation
Mometasone 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, breastfeeding should be discontinued

4.7 Effects on ability to drive and use machines

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	
Not known	Infection, furuncle
Very rare	Folliculitis
Nervous system disorders	
Not known	Paraesthesia,
Very rare	Burning sensation
Skin and subcutaneous tissue disorders	Dermatitis contact, skin hypopigmentation,
Not known	hypertrichosis, skin striae, dermatitis acneiform,
Very rare	skin atrophy
General disorders and administration site conditions	Pruritus
Not known	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 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.

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 <National reporting system>.

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

Mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.
Like other topical corticosteroids, Mometasone Furoate has anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids. In general, is unclear. However, corticosteroids are thought to act by induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2

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 ointment 0.1% 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

There are no findings of relevance other than those mentioned elsewhere in the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Hard paraffin wax
Petroleum jelly
Liquid paraffin
Monopropylene Glycol

6.2 Incompatibilities

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

6.3 Shelf life
24 Months.

6.4 Special precautions for storage
Store below 30 °C.

6.5 Nature and contents of container
Collapsible Aluminium tubes
Pack sizes of 5g.

6.6 Special precautions for disposal and other handling
Not applicable.

7. Marketing authorization holder

Registrant:
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8. **Marketing authorization number(s)**

H2021/CTD6892/13373

9. **Date of first authorization/renewal of the authorization**
2021 September 23

10. **Date of revision of the text**
2021 September 23