Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mometasone Furoate 0.1% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of ointment contains 1 mg of mometasone furoate (0.1% w/w mometasone furoate).
Excipient with known effect: 20 mg propylene glycol monopalmitostearate per gram of ointment (2.0% w/w)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

Opaque ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Mometasone Furoate 0.1% w/w Ointment is indicated for the treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis.

This medicinal product is indicated in adults and children above 6 years of age.

4.2 Posology and method of administration

Posology
Adults, including elderly patients, adolescents and children aged 6 years and over: A thin film of Mometasone Furoate 0.1% w/w Ointment should be applied to the affected areas of skin once daily. One fingertip unit (a line from the tip of an adult index finger to 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 clinical improvement.

Mometasone Furoate 0.1% w/w Ointment 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.

Paediatric population
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.

Children below 6 years: Mometasone Furoate 0.1% Ointment is not recommended for use in children below 6 years of age due to insufficient data on safety (see section 4.8).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or to any other corticosteroids.

Mometasone Furoate 0.1% w/w Ointment 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 0.1% Ointment should not be used on wounds or on skin which is ulcerated.

4.4 Special warnings and precautions for use

If irritation or sensitisation develop with the use of Mometasone Furoate 0.1% w/w Ointment, 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.

Paediatric population
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 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.

Visual disturbance
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.

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame and is a serious fire hazard. Patients should be warned of the risk of severe burns and advised not to smoke or go near naked flames when using this product. Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipient(s)
Propylene glycol monopalmitostearate
Propylene glycol 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 interactions

None stated.

4.6 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 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.

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 0.1% w/w Ointment 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 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
Eye disorders	Vision, blurred (see also section 4.4)
Not known	
Skin and subcutaneous tissue disorders	
Not known	Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy
Very rare	Pruritus
General disorders and administration site conditions	
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
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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: Corticosteroids, Dermatological preparations; Corticosteriods, potent (Group III) 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

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone furoate ointment 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 findings of relevance other than those mentioned elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol
White beeswax
Propylene glycol monopalmitostearate
Dilute phosphoric acid

White soft paraffin
Purified water

6.2 Incompatibilities

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

6.3 Shelf life

2 years.
In-use shelf life: 3 months

6.4 Special precautions for storage

Store below 30 °C.

6.5 Nature and contents of container

Collapsible aluminium tubes internally coated with an epoxy resin based lacquer and closed with a polypropylene cap.

Pack sizes: 30g, 60g or 100g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Auden Mckenzie (Pharma Division) Ltd
Whiddon Valley
Barnstaple
North Devon
EX32 8NS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA1352/018/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 20th July 2012
Date of Last Renewal: 25th May 2017

10 DATE OF REVISION OF THE TEXT

September 2019