SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mometasone furoate 0.1% w/w Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect: 20 mg propylene glycol monopalmitostearate/gram ointment and traces, up to a maximum of 0.015 mg butylhydroxytoluene (E321)/ gram ointment.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

A translucent white soft, uniform and smooth ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mometasone furoate 0.1% w/w Ointment is indicated for the symptomatic treatment of inflammatory and pruritic skin conditions which respond to external treatment with glucocorticoids, such as atopic dermatitis and psoriasis (excluding widespread plaque psoriasis).

Mometasone furoate 0.1% w/w Ointment should be preferably used to treat very dry, scaly and cracked skin complaints where a topical mometasone preparation is indicated.

4.2 Posology and method of administration

Posology

Adults, including older people and children aged 2 years and over: A thin film of Mometasone furoate 0.1% w/w Ointment should be applied to the affected skin area once daily until improvement is seen.

The frequency of application should then be decreased gradually.

Strong topical corticosteroids generally should not be applied to children or to the face without close monitoring by the physician. The amount applied should be limited to the least amount compatible with an effective therapeutic regimen and duration of the treatment should be no longer than 5 days (see section 4.4).

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.

Use of a weaker corticosteroid is often advisable when there is a clinical improvement.

Paediatric population
Children below 2 years:

Mometasone furoate is a potent group III glucocorticoid. It is not recommended for use in children below 2 years due to insufficient data on safety.

Method of Administration

Cutaneous use.

4.3 Contraindications

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

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, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections of the skin if causal therapy is not administered concomitantly, varicella, tuberculosis, syphilis or post-vaccine reactions.

Mometasone furoate 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.

Glucocorticoids can mask, activate or worsen a skin infection.

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 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.

Visual disturbances
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.

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 2 years of age have not been established, Mometasone furoate 0.1% w/w Ointment is not recommended in this age group. Mometasone furoate may be used with caution in paediatric patients 2 years of age or older, although the safety and efficacy of the use of mometasone furoate for longer than 3 weeks have not been established.

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 face, courses should be limited to 5 days. 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 is not for ophthalmic use, including the

eyelids because of the very rare risk of glaucoma simplex or subcapsular cataract.

Mometasone furoate 0.1% w/w Ointment contains propylene glycol which may cause skin irritation and also butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membrane.

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 Interaction with other medicinal products and other forms of interaction

During treatment with mometasone ointment in the genital or anal area, the excipient of white soft paraffin and the simultaneous use of latex condoms can lead to a reduction in tensile strength, reducing the safety of the condoms.

4.6 Fertility, pregnancy and lactation

Pregnancy

During pregnancy treatment with Mometasone furoate 0.1% w/w Ointment 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 (see section 5.3). 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 0.1% w/w Ointment 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 should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. During breast-feeding mometasone ointment should not be used on the breast area. 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

Mometasone furoate 0.1% w/w Ointment has no or negligible influence on the ability to drive and use machines.

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 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data)	
Infections and infestations	
Very rare	Folliculitis
Not known	Infection, furuncle
Endocrine disorders	

Rare	Adrenal cortex inhibition
Nervous system disorders	
Very rare	Burning sensation
Not known	Paraesthesia
Eye disorders	
Not known	Blurred vision (see section 4.4)
Skin and subcutaneous tissue disorders	
Common	Tingling, stinging sensation
Uncommon	Papular rosacea-like dermatitis (facial skin), pustules, secondary infection, capillary fragility (ecchymoses), skin striae, skin atrophy
Rare	Hypertrichosis, sensitisation (mometasone)
Very rare	Pruritus
Not known	Dermatitis contact, skin hypopigmentation, dermatitis acneiform
General disorders and administration site conditions	
Not known	Application site pain, application site reactions

Rare cases of hyperpigmentation have been reported in connection with other steroids and may therefore occur with Demoson.

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: stinging, dry skin, skin irritation, perioral dermatitis, allergic contact dermatitis, skin maceration, miliaria and telangiectasia.

An increased risk of systemic effects and local adverse reactions exists with frequent dosing, treatment of large areas or in the long term and also the treatment of intertriginous areas or with occlusive dressings.

Paediatric population

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 to body weight ratio (see section 4.4).

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

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

Reasonable symptomatic treatment should be initiated. If necessary, problems with the electrolyte balance must be treated.

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.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, potent (group III), ATC code: D07AC13

Mometasone furoate is a potent glucocorticoid, group III.
Mometasone furoate, is a synthetic, non-fluorinated glucocorticoid with a furoate ester in position 17.

Like other corticosteroids for external use, mometasone furoate exhibits marked anti-inflammatory activity, antipruritic and anti-allergic effects and marked anti-psoriatic activity in standard animal predictive models.

Mometasone furoate was shown to have an equivalent pharmacodynamic (vasoconstriction) response profile to the reference ointment product containing 1 mg/g mometasone furoate when applied to normal skin. The Negative Area Under Effect Curve ratio of mometasone furoate to the reference product in the vasoconstrictor assay was 111% (90% CI 103-121%).

The therapeutic index of mometasone furoate (a ratio of desired to unwanted effects) determined from relevant literature data suggests that mometasone belongs to a category of topical glucocorticoids, in which desired effects clearly outweigh unwanted effects.

In the croton oil assay in mice, mometasone (ED_{50} = 0.2 µg/ear) was equipotent to betamethasone valerate after single application and about 8 times as potent after five

applications (ED_{50} = 0.002 µg/ear/day versus 0.014 µg/ear/day).

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

5.2 Pharmacokinetic properties

Absorption
Results from percutaneous absorption studies have indicated that systemic absorption following topical application of mometasone furoate ointment 0.1% is minimal. The results show that about 0.7% of the active ingredient is absorbed by the intact skin in 8 hours (without using an occlusive dressing).

Distribution
Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.

5.3 Preclinical safety data

Acute toxicity

Animal species	Type of application	LD_{50} (mg/kg)
Mouse	subcutaneous	200-2000
Rat	subcutaneous	200
Dog	subcutaneous	> 200
Mouse	oral	> 2000
Rat	oral	> 2000

Chronic toxicity
In various toxicity studies with chronic use in which excessive quantities of the active ingredient (670 times the therapeutic dose) were applied over 6 months, only symptoms typical of corticoid overdose were found: reduced weight gain; muscular atrophy; distended abdomen; decrease in lymphocytes and eosinophilic granulocytes and increase in neutrophilic leucocytes; increase in serum transaminases (SGPT and SGOT), cholesterol and triglycerides; lipidemia; organ changes (atrophy of the spleen and thymus, local skin atrophy, increases in liver and kidney weight and reduced osteogenesis).
These changes were generally more pronounced and more frequent in animals which were given the comparison substance, betamethasone valerate.
Neither of the two substances exhibited unusual systemic effects.

Genotoxicity
Tests on gene mutations were negative. However, mometasone induced chromosome mutations in-vitro but only at cell-toxic concentrations. Similar

effects were not observed in thorough in-vivo tests, so a mutagenic risk can be ruled out with sufficient certainty.

Carcinogenicity
Long-term carcinogenicity studies of mometasone furoate have been conducted by the inhalation route in rats (2 years) and mice (19 months). No statistically significant increase in the incident of tumours was observed at doses up to 67 mcg/kg in rats or 160 mcg/kg in mice.

Reproductive toxicity
Animal tests on the effect of mometasone furoate on embryonic development in rabbits revealed depressed body weight from 0.15 mg/kg/BWT upwards. After topical treatment of rabbits, the progeny suffered various types of malformation, such as crooked front paws, cleft palate, gallbladder agenesis and umbilical hernia. In the rat, embryolethal effects from 7.5 µg/kg/BWT (subcutaneous) and poor development from 0.3 mg/kg/BWT (topical) (depressed body weight, delayed ossification) and substance-related increase in umbilical hernia were observed. When the drug was administered to mothers close to the birth date, protracted labour and difficult births were observed.

Mometasone furoate had no effects on the fertility of rats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol
Phosphoric acid, concentrated (for pH – adjustment)
Propylene glycol monopalmitostearate
Beeswax, white
Paraffin, white soft
Butylhydroxytoluene (E321) (as an antioxidant in paraffin, white soft)
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

After first opening: 12 weeks

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

The ointment is filled in aluminium tubes fitted with a white high density polyethylene piercing screw cap in a cardboard carton. Carton of 1 tube.

Pack sizes:
Tubes with 10 g, 15 g, 20 g, 30 g, 50 g, 60 g and 100 g of ointment
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Generics [UK] Limited t/a Mylan

Station Close

Potters Bar

Hertfordshire

EN6 1TL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 04569/0886

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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29/06/2020