1. NAME OF THE MEDICINAL PRODUCT

Elocom® Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone Furoate 0,1 % w/w

Propylene glycol stearate 2,0 % w/w

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Elocom Ointment 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 Elocom 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 and duration of treatment should be no more than 5 days.

4.3 Contra-indications

Elocom is contra-indicated 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. Elocom should not be used on wounds or skin which is ulcerated. Elocom should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the excipients listed in section 6.1.

4.4. Special Warnings and Precautions for Use

If irritation or sensitisation develop with the use of Elocom, treatment should be withdrawn and appropriate therapy instituted.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, hyperglycaemia 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 Elocom 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.

Elocom Ointment contains propylene glycol which may cause skin irritation.

Elocom topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or sub-capsular cataract.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 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.

4.5. Interactions with other Medicaments and other forms of Interaction

None stated

4.6. Fertility, Pregnancy and Lactation

Pregnancy

During pregnancy and lactation treatment with Elocom 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 Elocom 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, Elocom should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

Lactation

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Elocom 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 Elocom 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	
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
Eye Disorders	
Not known	Vision blurred(see also section 4.4)

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. 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: Mometasone, 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 0,7 % 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

Hexylene glycol

Phosphoric acid

Propylene glycol stearate

White beeswax

White soft paraffin

Purified water

6.2. Incompatibilities

None known

6.3. Shelf Life

36 months

6.4. Special Precautions for Storage

Store at or below 30 °C.

Keep out of reach of children.

6.5. Nature and Contents of Container

5, 15, 30, 45, 50 and 100gm aluminium tube with low density polyethylene cap or laminated tubes with high density polyethylene head and polypropylene cap.

Not all pack sizes may be marketed.

6.6 Instructions for Use, handling and disposal

Not applicable

7. MARKETING AUTHORISATION HOLDER

MSD (Pty) Ltd, 117 16th Road, Halfway House 1685, South Africa

8. NAME AND ADDRESS OF THE MANUFACTURER

Schering-Plough Labo N.V., Industriepark 30, B-2220 Heist-op-den-berg, Belgium

9. MARKETING AUTHORISATION NUMBER

ETHIOPIA	SCH/BEL/016
KENYA	7066
NIGERIA (NAFDAC Reg No.)	TBA
TANZANIA	TZ17H0058
UGANDA	3499/13/00
ZAMBIA	042/005
ZIMBABWE	TBA

10. SCHEDULING STATUS

POM

R_X ONLY

ZIMBABWE SCHEDULING: TBA

11. DATE OF FIRST AUTHORISATION

ETHIOPIA	18/08/2016
KENYA	10/09/1996
NIGERIA	TBA
TANZANIA	09/03/2017
UGANDA	22/03/2000
ZAMBIA	08/05/2007
ZIMBABWE	TBA

12. DATE OF PUBLICATION

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