1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

1. Name of medicinal product: Elica-M Cream

2. Qualitative and quantitative composition:

(Mometasone Furoate 0.1% + Miconazole Nitrate 2%)
For excipients, please see 6.1

3. Pharmaceutical form:

Each gram of the Cream contains:
Mometasone Furoate 1.0 mg
Miconazole Nitrate 20 mg
For excipients, see section 6.1.

4. Clinical particular:

4.1 Therapeutic indication:

Mometasone Furoate & Miconazole Nitrate 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 & Miconazole Nitrate 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:

Mometasone Furoate & Miconazole Nitrate 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 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 & Miconazole Nitrate should not be used on wounds or on skin which is ulcerated**.** Mometasone Furoate & Miconazole Nitrate should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the ingredients in this medicine. Intertriginous eczema including inflammatory intertrigo, perianal and genital dermatitis. Organisms which are susceptible to miconazole are dermatophytes and pathogenic yeasts (e.g. Candida spp.). Also many Gram-positive bacteria including most strains of Streptococcus and Staphylococcus

4.4 Special warning with other medicinal products and other forms of interaction:

If irritation or sensitisation develops with the use of Mometasone Furoate & Miconazole Nitrate, treatment should be withdrawn and appropriate therapy instituted.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 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.

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 & Miconazole Nitrate 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 & Miconazole Nitrate 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 Pregnancy and Lactation:

During pregnancy and lactation treatment with Mometasone Furoate & Miconazole Nitrate 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 & Miconazole Nitrate 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 & Miconazole Nitrate should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Mometasone Furoate & Miconazole Nitrate 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 Elocon 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 Very rare Nervous system disorders Not known Very rare Skin and subcutaneous tissue disorders Not known Very rare General disorders and administration site conditions Not known Eye disorders Not Known	Infection, furuncle Folliculitis Paraesthesia, Burning sensation Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy Pruritus Application site pain, application site reactions Vision blurred (see also section 4.4)

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.

4.9 Overdose:

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic pituitaryadrenal 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 & Miconazole Nitrate 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.

Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

5.2 Pharmacokinetic Properties:

Pharmacokinetic studies have indicated that systemic absorption following topical application of Mometasone Furoate & Miconazole Nitrate is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterization 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 particular
6.1 List of excipients:

- Cetomacrogal-1000
- Cetostearyl Alcohol
- Chlorocresol
- White Soft Paraffin
- Liquid Paraffin
- Propylene Glycol
- Disodium Hydrogen Phosphate Anhydrous
  Or Disodium Hydrogen Phosphate Dihydrate
- Citric Acid Anhydrous
  Or Citric Acid Monohydrate
- Phosphoric Acid 1M
- Or Sodium Hydroxide 1 N
- Water Purified

6.2 Incompatibilities:
Not applicable
6.3 Shelf life:
24 Months

6.4 Special precautions for storage:
Do not store above 30°C.

Advice to be used within 3 months of tube opening.

6.5 Nature and content of the container:
30 g Aluminum Collapsible tube in Carton along with PIL.

6.6 Instructions for use and handling (and disposal):
Not applicable

7. Marketing authorization holder:
JAMJOOM PHARMACEUTICALS COMPANY
P.O. Box 6267
Jeddah 21442
Tel: +966 12 6081111
Fax: +966 12 6081222
Kingdom of Saudi Arabia

8. Marketing authorisation number(s).
B4-7659

9. Date of first authorisation/renewal of the authorization.
31-Oct-2017

10. Date of revision of the text.
Augest-22