SCHEDULING STATUS S4

1 NAME OF MEDICINE

ELOMET® CREAM

ELOMET® OINTMENT

ELOMET® LOTION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ELOMET Cream contains 1 mg mometasone furoate (micronised).

Each gram of ELOMET Ointment contains 1 mg mometasone furoate (micronised).

Each gram of ELOMET Lotion contains 1 mg mometasone furoate (micronised).

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

ELOMET Cream:	A smooth, white to off-white cream.
ELOMET Ointment:	A smooth, white to off-white, opaque ointment.
ELOMET Lotion:	A colourless to light yellow, smooth lotion

4.CLINICAL PARTICULARS

4.1. Therapeutic indications

ELOMET is indicated for the relief of the inflammatory manifestations of psoriasis and corticosteroid-responsive dermatoses. ELOMET Lotion may be applied to scalp lesions.

4.2. Posology and method of administration

A thin film of ELOMET Cream or Ointment should be applied to completely cover the affected area once daily.

ELOMET Cream and Ointment may be used with caution in paediatric patients 2 years of age or older. Safety and efficacy of ELOMET Cream and Ointment in paediatric patients for more than 3 weeks of use have not been established. Use in paediatric patients under 2 years of age is not recommended.

A few drops of ELOMET Lotion should be applied to the affected skin area and massaged gently and thoroughly into the skin once daily.

Treatment should be discontinued when the dermatologic disorder is controlled. According to clinical response, duration of therapy may vary from a few days to a longer period of time. However, treatment should not be continued for more than 3 weeks without patient re-evaluation.

4.3. Contraindications

ELOMET is contraindicated in those patients with a history of sensitivity reactions to any of its components.

ELOMET is contraindicated in the treatment of herpes simplex, vaccinia or varicella.

4.4.Special warnings and precautions for use

ELOMET is **not** for ophthalmic use.

If irritation or sensitisation develops with the use of ELOMET, treatment should be discontinued and appropriate therapy instituted.

Systemic absorption of ELOMET may occur, particularly under the following conditions:

- when large quantities are used
- when application is made to wide areas of the body, to damaged skin and
- when the occlusive dressing technique is applied.

Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur. These effects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been rarely reported.

Evidence of HPA axis suppression may be evaluated by periodic determinations of ACTH stimulation, AM plasma cortisol and urinary free cortisol tests.

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.

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.

Long-term continuous treatment with ELOMET should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses. These changes are particularly likely to occur on the face and when occlusive dressings are used.

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted.

ELOMET should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced.

ELOMET should be used with caution near the eyes.

ELOMET should be used for short courses only. Safety for use longer than 3 weeks has not been established. Regular review should be made of the necessity for continuing therapy.

ELOMET should not be used in the nappy areas in infants for flexural eruptions and ideally it should not be applied to infants and young children (under 2 years) at all.

Since safety and efficacy of ELOMET Cream and Ointment have not been established in paediatric patients below 2 years of age, its use in this age group is not recommended.

The treatment of psoriasis with ELOMET may provoke the pustular form of the disease.

ELOMET should not be applied to any skin crease areas.

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when ELOMET skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

4.5 Interaction with other medicines and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

Pregnancy

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, ELOMET should not be used during pregnancy.

Breastfeeding

The use of ELOMET is not recommended for mothers who are breastfeeding.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria and blurred vision.

Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9Overdose

See Special warnings and precautions for use (section 4.4) and Undesirable effects (section 4.8).

Symptoms: Excessive or prolonged use of ELOMET can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, but may also produce manifestations of hypercorticism, including Cushing syndrome.

Treatment: Treatment is symptomatic and supportive. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.13.4.1 Corticosteroids with or without anti-infective agents.

ELOMET has anti-inflammatory, antipruritic and vasoconstrictive actions. ELOMET falls within the medium range of potency.

6.PHARMACEUTICAL PARTICULARS

6.1.List of excipients

ELOMET Cream: hexylene glycol, hydrogenated soybean lecithin, phosphoric acid, titanium dioxide, starch octenylsuccinate, white wax, white soft paraffin and purified water.

ELOMET Ointment: hexylene glycol, phosphoric acid, propylene glycol stearate, white beeswax, white soft paraffin and purified water.

ELOMET Lotion: hydroxypropylcellulose, isopropyl alcohol, monobasic sodium phosphate, phosphoric acid, propylene glycol and purified water.

6.2.Incompatibilities

Not applicable.

6.3.Shelf life

ELOMET Cream: 24 months

ELOMET Ointment: 36 months

ELOMET Lotion: 24 months

6.4. Special precautions for Storage

ELOMET Cream and Ointment: Store at or below 25 °C. Protect from light.

ELOMET Lotion: Store at or below 30 °C. Protect from light.

6.5. Nature and contents of Container

ELOMET Cream:	Tubes of 10 g, 15 g, 20 g, 30 g and 45 g.
ELOMET Ointment:	Tubes of 10 g, 15 g, 20 g, 30 g and 45 g.
ELOMET Lotion:	White, plastic bottles of 20 mL, 30 mL and 100 mL.

Not all pack sizes may be marketed.

6.6. Special Precautions for Disposal

No special requirements.

7.HOLDER OF CERTIFICATE OF REGISTRATION

Organon South Africa (Pty) Ltd

Spaces, 1st Floor

22 Magwa Crescent, Gateway West

Waterfall City, Midrand, 2090

South Africa

8. REGISTRATION NUMBER(S)

ELOMET Cream: 31/13.4.1/0546

ELOMET Ointment: 31/13.4.1/0547

ELOMET Lotion: 31/13.4.1/0591

9. DATE OF FIRST AUTHORISATION

Date of Registration:

ELOMET Cream: 02 August 1989

ELOMET Ointment: 02 August 1989

ELOMET Lotion: 19 September 1991

10. DATE OF REVISION OF THE TEXT

28 June 2023

S-CCDS-MK-0887-MTL-082017; SAHPRA PV Directive PVC 120 dated 15 September 2022.