1.3.1.1.1 Professional Information

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

MACEPATAN FATTY OINTMENT 1 mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of MACEPATAN FATTY OINTMENT contains 1 mg methylprednisolone aceponate.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Fatty Ointment.

MACEPATAN FATTY OINTMENT is a white to yellowish translucent ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

MACEPATAN FATTY OINTMENT is indicated for endogenous eczema (atopic dermatitis, neurodermatitis), contact eczema, dyshidrotic and other eczemas.

4.2. Posology and method of administration

Posology

MACEPATAN FATTY OINTMENT is applied thinly once per day to the diseased areas of skin.

In general, the duration of use should not exceed 12 weeks in adults.

Very dry skin conditions and chronic stages of skin disease require an anhydrous base. The occlusive effect of the fatty ointment base promotes the healing procedure.

Paediatric population

The duration of use should not exceed 4 weeks in children.

MACEPATAN FATTY OINTMENT should not be applied to infants and young children (see section 4.3).

Method of administration

For external topical use.

4.3. Contraindications

MACEPATAN FATTY OINTMENT is contraindicated in:

- Patients with hypersensitivity to methylprednisolone aceponate or to any excipients in MACEPATAN FATTY OINTMENT (see section 6.1).
- Tuberculous or syphilitic processes, post-vaccination skin reactions present in the area to be treated.
- Viral diseases (e.g. varicella/herpes zoster, herpes simplex, vaccinia, chickenpox, shingles).
- Pregnancy. Corticosteroids, such as MACEPATAN FATTY OINTMENT, have been shown to be teratogenic in animals following dermal application. As these medicines

are absorbed percutaneously, teratogenicity following topical application cannot be excluded.

- Children under four months due to lack of experience.
- If rosacea, ulcers, atrophic skin diseases, acne vulgaris or perioral dermatitis are present, MACEPATAN FATTY OINTMENT must not be applied to the face.

4.4. Special warnings and precautions for use

Hypersensitivity

If signs of hypersensitivity develop, MACEPATAN FATTY OINTMENT should be discontinued and appropriate treatment instituted.

Long-term continuous treatment with topical corticosteroids, such as MACEPATAN FATTY OINTMENT, should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, striae, dilatation of superficial blood vessels, telangiectasiae and ecchymoses.

These changes are particularly likely to occur on the face and when occlusive dressings are used.

Acneiform skin conditions can occur under therapy with potent corticoids such as MACEPATAN FATTY OINTMENT.

Treatment should be discontinued if symptoms such as cutaneous atrophy occur.

Systemic absorption of topically applied corticosteroids may occur, particularly under the following conditions:

- when large quantities are used,
- when application is made to wide areas of the body, or to damaged skin,

- when potent topical corticosteroids are used,
- 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 Cushingoid state may be produced.

Benign increased intracranial pressure has been rarely reported.

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted. If fungal infections represent, a topically active antimycotic should be applied.

Any spread of infection requires withdrawal of topical corticosteroid therapy.

Topical corticosteroids should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced. If rosacea or perioral dermatitis is present, MACEPATAN FATTY OINTMENT must not be applied to the face. MACEPATAN FATTY OINTMENT should not be allowed to come into contact with the eyes when being applied to the face.

MACEPATAN FATTY OINTMENT should not be allowed to come into contact with deep open wounds or mucosae.

Regular review should be made of the necessity for continuing therapy.

The treatment of psoriasis with potent topical corticosteroids may provoke the pustular form of the disease.

MACEPATAN FATTY OINTMENT should not be applied to skin crease areas.

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.

As known from systemically administered corticosteroids, glaucoma may also develop from using topical corticosteroids (e.g. after large-dose or extensive application over a prolonged period, application under occlusive dressings, or application to skin around or near the eyes).

Topical steroid withdrawal syndrome

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 delicate 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.

Paediatric population

MACEPATAN FATTY OINTMENT 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 (see section 4.3).

In infants and children, plastic pants and napkins may act as occlusive dressings and increase absorption. Because of children's larger skin surface area to bodyweight ratio, paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than adults. Chronic/long-term corticosteroid therapy may interfere with growth and development of children. Use of topical corticosteroids in children should be limited to the least amount required for therapeutic effect.

4.5. Interaction with other medicines and other forms of interaction

No specific information exists on interactions with other medicines.

4.6. Fertility, pregnancy and lactation

Pregnancy

The use of MACEPATAN FATTY OINTMENT is contraindicated in pregnancy (see section 4.3).

Breastfeeding

MACEPATAN FATTY OINTMENT should be used with caution in nursing mothers.

It is not known whether methylprednisolone aceponate, as in MACEPATAN FATTY OINTMENT, is secreted in breast milk.

Nursing mothers should avoid treatment over large areas, prolonged use or occlusive dressings. MACEPATAN FATTY OINTMENT should not be applied to the chest area during breastfeeding to avoid possible ingestion by infants.

Fertility

No data available.

4.7. Effects on ability to drive and use machines

MACEPATAN FATTY OINTMENT may cause blurred vision (see section 4.8).

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that MACEPATAN FATTY OINTMENT does not adversely affect their ability to do so safely (see section 4.4 and/or 4.8).

4.8. Undesirable effects

a) Summary of the safety profile

Most frequently observed side effects include application site folliculitis and application site burning.

b) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Immune system disorders		Hypersensitivity	
Endocrine disorders			*Adrenal suppression, growth retardation in children, Cushingoid features

Nervous system disorders		*Benign intracranial hypertension	
Eye disorders			Blurred vision
Skin and subcutaneous tissue disorders	Folliculitis		hypertrichosis, perioral dermatitis,
		Atrophic changes in the skin with long-term continuous use, leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae, ecchymoses,	
		skin fissures	Acne
			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),
General disorders and administrative site conditions	Application site folliculitis, Application site burning	application site pustules, application site vesicles, application site pruritus, application site pain, application site erythema, application site papules	

**Systemic absorption reactions (see section 4.4)*

c) Description of selected adverse reactions

The following local side effects have been reported in post marketing data and may occur: skin atrophy, skin striae, application folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discolouration, and hypersensitivity to any of the ingredients of the

formulation. Systemic effects due to absorption may occur when topical medicines containing corticoids are applied.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

Excessive dosing may occur with prolonged or intensive topical use (see sections 4.4 and 4.8). Acute toxicity studies with methylprednisolone aceponate (namely oral ingestion, or single dermal application to a large area, under conditions favourable to absorption) do not indicate that any acute intoxication is expected.

Treatment

If any symptoms of overdosage occur, treatment must be discontinued.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A.13.4.1 Corticosteroids without anti-infective agents.

Pharmacotherapeutic group: Corticosteroids, potent (group III)

ATC code: D07AC14

Mechanism of action

After topical application, MACEPATAN FATTY OINTMENT has anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of action of methylprednisolone aceponate is not completely understood. It is known that methylprednisolone aceponate itself binds to the intracellular glucocorticoid receptor and this is especially true for the principal metabolite methylprednisolone-17-propionate, which is formed after cleavage in the skin.

The steroid receptor complex binds to certain regions of DNA, thereby triggering a series of biological effects. Binding of the steroid receptor complex results in induction of macrocortin synthesis. Macrocortin inhibits the release of arachidonic acid and thus the formation of inflammatory mediators such as prostaglandins and leukotrienes.

The immunosuppressive action of glucocorticoids can be explained by inhibition of cytokine synthesis and an antimitotic effect, which so far is not well understood. Inhibition of the synthesis of vasodilating prostaglandins or potentiation of the vasoconstrictive effect of adrenalin finally results in the vasoconstrictive activity of glucocorticosteroids.

5.2. Pharmacokinetic properties

Absorption

Methylprednisolone aceponate is bioavailable. When applied topically the concentration of methylprednisolone aceponate is highest in the outer layer of the epidermis (stratum corneum) and decreases progressively in the deeper strata.

The degree of percutaneous absorption of methylprednisolone aceponate varies according to the state of the skin (intact/inflamed/damaged), and the conditions of application (ope/occlusion). Studies using the fatty ointment-formulation in juvenile and adult patients with neurodermatitis and psoriasis have shown that the percutaneous absorption on open application was slightly (≤ 2,5 %) greater than the percutaneous absorption in volunteers with normal skin (0,2 % to 1,5 %). Occlusive dressing increased percutaneous absorption. When the superficial horny layer is removed before application of methylprednisolone aceponate, the corticoid levels in the skin are about three times higher than after application to intact skin.

Distribution

The systemic effects of methylprednisolone aceponate are minimal in both man and animals following application of a topically effective dose. After treatment of large areas in patients with skin disorders, the plasma cortisol values remain within the normal range; circadian cortisol rhythm is maintained, and no reduction of cortisol has been ascertained in 24-hour urine.

Biotransformation

Methylprednisolone aceponate is hydrolysed in the epidermis and dermis to the principal metabolite, 6α-methylprednisolone-17-propionate. This metabolite binds to the intracellular glucocorticoid receptor with higher affinity than methylprednisolone aceponate. The binding of 6α-methylprednisolone-17-propionate to the receptor is an indicator of “bioactivation” in the skin.

After absorption into the systemic circulation, the primary hydrolysis product of methylprednisolone aceponate, 6α-methylprednisolone-17-propionate, is rapidly conjugated with glucuronic acid, and as a result, inactivated.

Elimination

The principal metabolites of methylprednisolone aceponate are eliminated primarily via the kidneys. The half-life is about 16 hours. Following intravenous administration, excretion via the urine and faeces was complete within 7 days. There is no accumulation of methylprednisolone aceponate or metabolites in the body.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Hydrogenated castor oil, liquid paraffin, microcrystalline wax, white soft paraffin

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at or below 25 °C.

Keep in the original container until required for use.

Keep the tube container well closed.

6.5. Nature and contents of container

20 g or 50 g is packed in a closed end nozzle lacquered aluminium tube with white polypropylene cap with piercing tip, contained in an outer carton.

Not all packs or pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

Hotline: 0800 122 912

8. REGISTRATION NUMBER

59/13.4.1/0670

9. DATE OF FIRST AUTHORISATION

30 June 2026

10. DATE OF REVISION OF TEXT

30 June 2026

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.