1.3.1.1. PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

ASPEN MOMETASONE CREAM 1,0 mg/1,0 g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1,0 g of ASPEN MOMETASONE CREAM contains 1,0 mg mometasone furoate.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

A stiff white to off-white oleaginous cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

ASPEN MOMETASONE CREAM is indicated for the relief of inflammatory manifestations of psoriasis and corticosteroid-responsive dermatoses.

4.2. Posology and method of administration

For topical administration.

A thin film of ASPEN MOMETASONE CREAM should be applied to completely cover the whole affected area once daily.

Treatment should be discontinued once the condition is under control.

Duration of therapy is dependent on clinical response and may vary from a few days to a longer period of time. It should, however, not be continued for longer than three weeks without the patient being re-evaluated.

Paediatric population

ASPEN MOMETASONE CREAM may be used with caution in paediatric patients from the age of two years and older.

Safety and efficacy of ASPEN MOMETASONE CREAM 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.

4.3. Contraindications

ASPEN MOMETASONE CREAM is contraindicated in:

- Patients with hypersensitivity to mometasone or to any excipients in ASPEN MOMETASONE CREAM (see section 6.1).
- Viral infections such as *herpes simplex*, *vaccinia* and *varicella*.
- Untreated fungal infections.

4.4. Special warnings and precautions for use

If irritation or sensitisation develop with the use of ASPEN MOMETASONE CREAM, treatment should be discontinued, and appropriate therapy instituted.

Systemic absorption of topical corticosteroids, such as mometasone, as in ASPEN MOMETASONE CREAM, 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 glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid such as mometasone, as in ASPEN MOMETASONE CREAM, to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

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.

As with all potent topical glucocorticoids, such as mometasone, as in ASPEN MOMETASONE CREAM, 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.

ASPEN MOMETASONE CREAM is not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

Use with caution near the eyes.

Safety of use for more than three weeks has not been established and ASPEN MOMETASONE CREAM should therefore be used for short courses only.
Long term continuous or inappropriate use of topical steroids such as mometasone, as in ASPEN MOMETASONE CREAM, 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. ASPEN MOMETASONE CREAM should not be applied to any skin crease areas and especially not in the nappy area of infants. 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.

Glucocorticoids such as mometasone, as in ASPEN MOMETASONE CREAM, can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

If ASPEN MOMETASONE CREAM is used for the treatment of psoriasis, the pustular form of the disease may be provoked. Topical steroids such as mometasone, as in ASPEN MOMETASONE CREAM, 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.

If secondary bacterial infection is present, suitable concomitant antimicrobial therapy should be applied. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

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 serious chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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.

Paediatric Population

Safety and efficacy of ASPEN MOMETASONE CREAM in paediatric patients for more than three weeks of use have not been established. Use in paediatric patients under the age of two years is not recommended.

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, ASPEN MOMETASONE CREAM in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

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.

4.5. Interaction with other medicines and other forms of interaction

None stated

4.6. Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

Pregnancy

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these medicines may be absorbed percutaneously, teratogenicity following topical application cannot be excluded. ASPEN MOMETASONE CREAM should therefore not be used during pregnancy.

Breastfeeding

ASPEN MOMETASONE CREAM is not recommended for breastfeeding mothers.

Fertility

There are no data available.

4.7. Effects on ability to drive and use machines

ASPEN MOMETASONE CREAM has no or negligible influence on the ability to drive or operate machinery.

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown (cannot be estimated from the available data)**
Infections and infestations			Infection, furuncle
Endocrine disorders		Benign intracranial hypertension, Cushingoid state, depression of the hypothalamic- pituitary-adrenal axis, consequent suppression of the adrenal gland and growth retardation.	
Nervous system disorders		Burning sensation	Paraesthesia
Eye disorders			Vision blurred (see also section 4.4)
Skin and subcutaneous tissue disorders		Allergic contact dermatitis, burning, dryness, folliculitis, irritation, itching, secondary infection, skin atrophy, acneiform eruptions, perioral dermatitis, hypertrichosis, hypopigmentation, miliaria, maceration. skin thinning, loss of elasticity, dilation of superficial blood vessels, telangiectasia , ecchymosis, pruritus	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 pain, application site reactions

b) Description of selected adverse reactions

Skin and subcutaneous tissue disorders

Long-term continuous therapy with ASPEN MOMETASONE CREAM may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilation of superficial blood vessels, telangiectasia and ecchymosis, especially if applied to the face or if occlusive dressings are used. Discontinue treatment if irritation or sensitisation occurs and treat appropriately.

In facial dermatoses, ASPEN MOMETASONE CREAM should be used cautiously and for short periods only, as steroid rosacea-like facies may be produced.

Endocrine disorders

Systemic absorption may occur, especially when large quantities of the cream are used or applied to large areas of the body or to damaged skin and when an occlusive dressing technique is applied. This may result in benign intracranial hypertension, a Cushingoid state, depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland and growth retardation. These effects are most likely to be severe in children.

c) 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 area to body weight ratio.

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 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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

4.9. Overdose

Symptoms

Refer to Section 4.8.

Excessive or prolonged use of ASPEN MOMETASONE CREAM can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, which is usually reversible, but may also produce manifestations of hypercorticism, including Cushing's syndrome.

Treatment

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

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

Pharmacotherapeutic group: Corticoids, potent (group III)

ATC code: D07AC13

Mechanism of action

Mometasone is a medium-potency synthetic topical steroid that has anti-inflammatory, antipruritic and vasoconstrictive actions.

5.2. Pharmacokinetic properties

Absorption

A minimal amount of mometasone is absorbed after topical application to normal skin.

Elimination

That which is absorbed is metabolised in the liver and excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aluminium starch octenylsuccinate, beeswax white, ceteareth-20 and stearyl alcohol, hexylene glycol, phosphoric acid (for pH adjustment), propylene glycol stearate, purified water, titanium dioxide (C.I. 77891), white soft paraffin.

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

Keep well closed.

Keep in original packaging until required for use.

6.5. Nature and contents of container

20 g or 50 g cream are packed in an aluminium collapsible tube sealed with a white self-piercing, high density polyethylene cap and placed in a unit cardboard carton.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

A38/13.4.1/0668

9. DATE OF FIRST AUTHORISATION

25 November 2005

10. DATE OF REVISION OF TEXT

04 April 2024

Die Afrikaanse Professionele Inligting is op versoek beskikbaar.

Mediese Blitslyn: 0800 118 088.

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