1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINE FOR HUMAN USE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

CORTODERM OINTMENT 1,25 mg/5 g

CORTODERM CREAM 1,25 mg/5 g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g of CORTODERM OINTMENT contains 1,25 mg of fluocinolone acetonide.

Each 5 g of CORTODERM CREAM contains 1,25 mg of fluocinolone acetonide.

Preservative: Chlorocresol 0,1 % *m/m*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

CORTODERM OINTMENT is a soft white translucent ointment.

Cream

CORTODERM CREAM is a soft, smooth, white cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CORTODERM is indicated for:

- Steroid responsive dermatoses.

4.2 Posology and method of administration

Posology

CORTODERM OINTMENT:

Apply to the affected areas 2 to 3 times daily by gentle inunction or use with occlusive dressings.

CORTODERM CREAM:

Apply to the affected areas 2 to 3 times daily by gentle inunction.

Method of administration

For topical application.

4.3 Contraindications

CORTODERM is contraindicated in:

- Patients with a history of hypersensitivity to fluocinolone acetonide or to any excipients in CORTODERM (see section 6.1)
- Pregnancy.
- The treatment of herpes simplex, vaccinia or varicella.
- Long-term use in patients with diabetes mellitus or tuberculosis.
- Infants and young children.

4.4 Special warnings and precautions for use

Hypersensitivity

Treatment should be discontinued if unfavourable reactions are seen. Regular review should be made of the necessity for continuing therapy.

Wounds and infections

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted. CORTODERM should not be used to treat infections and ulcers of the leg. It causes delayed wound healing and increased liability to infections.

General

CORTODERM should not be applied to any skin crease areas.

CORTODERM should be used with caution near the eyes and should be used for short courses only. Application to the eyes has produced corneal ulcers, raised intraocular pressure, and reduced visual function.

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

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

CORTODERM should not be used on infants and young children.

Children may absorb proportionally larger amounts of topical corticosteroids, as in CORTODERM and thus be more susceptible to systemic toxicity.

Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema

4.5 Interaction with other medicines and other forms of interaction

Not known.

4.6 Fertility, pregnancy and lactation

Pregnancy

The use of CORTODERM is contraindicated in 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 CORTODERM should not be used during pregnancy.

Breastfeeding

It is not known whether topical administration of corticosteroids, as in CORTODERM, could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, caution should be exercised when topical corticosteroids, as in CORTODERM are administered to a breastfeeding woman.

Fertility

There are no data available

4.7 Effects on the ability to drive and use machines

CORTODERM has no or negligible influence on the ability to drive or operate machinery.

4.8 Undesirable effects

a) Summary of the safety profile

Systemic absorption of topically applied CORTODERM may occur, particularly under the following conditions, when large quantities are used, or when application is made to wide areas of the body or to damaged skin, and when the occlusive dressing technique is applied.

b) Tabulated list of adverse reactions

System organ class	Frequent	Less frequent	Frequency unknown (cannot be estimated from the available data)
Infections and infestations			Worsened and enhanced spread of local infections
Immune system disorders			Hypersensitivity reactions, including itching and irritation
Endocrine disorders			Depression of the hypothalamic - pituitary - adrenal axis, adrenal gland suppression, growth retardation in children, Cushingoid state.
Nervous system disorders			Benign intracranial hypertension
Skin and subcutaneous tissue disorders			Atrophy of the epidermis and dermal collagen (causing atrophic striae), drying and thinning of the skin, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses, increased fragility of cutaneous vessels resulting in bruising and purpura, Rosacea-like dermatitis*, perioral dermatitis*, hypopigmentation* and acneiform eruptions*, allergic contact dermatitis, folliculitis, hypertrichosis, withdrawal reactions

* These changes are particularly likely to occur on the face and when occlusive dressings are used. Occlusive dressings are associated with maceration of the skin and miliaria.

c) Description of selected adverse reactions

Endocrine disorders

Systemic absorption of topically applied CORTODERM may occur, particularly under the following conditions; when large quantities are used, or when application is made to wide areas of the body or 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, and may be precipitated by an infection or trauma. These effects are most likely to be severe in children. Growth retardation in children has been reported and a Cushingoid state may be produced.

Withdrawal reactions

These include 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. Health care providers are requested to report any suspected adverse drug 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/+27 (0)11 239 6200

4.6 Overdose

Symptoms

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Treatment

Treatment is supportive and symptomatic.

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: D07AC04

Mechanism of action

Fluocinolone acetonide is a potent topical corticosteroid which exhibits anti-inflammatory, vasoconstrictive, anti-pruritic and anti-allergic properties when applied locally to the skin and mucosa.

6. PHARMACOLOGICAL PROPERTIES

6.1 List of excipients

OINTMENT

Beeswax white, cholesterol, paraffin white soft, propylene glycol, stearyl alcohol.

CREAM

Cetyl alcohol, chlorocresol, emulsifying wax, liquid paraffin, propylene glycol, purified water, citric acid monohydrate (for pH adjustment), and disodium phosphate dodecahydrate (for pH adjustment).

6.2. Incompatibilities

Not applicable

6.3. Shelf life

CORTODERM OINTMENT:

36 months

CORTODERM CREAM:

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

Protect from light.

Store in well-closed containers.

Keep in original packaging until required for use.

6.5. Nature and contents of container

CORTODERM OINTMENT:

15 g is packed in a cylindrical, printed, epoxy phenolic lined, aluminium foil tube with a white high density polyethylene screw cap, and placed in a unit cardboard carton together with a leaflet.

500 g is packed in a white high density polyethylene jar with a white polypropylene screw cap, together with a leaflet.

CORTODERM CREAM:

15 g is packed in a cylindrical, printed, epoxy phenolic lined, aluminium foil tube with a white high density polyethylene screw cap, and placed in a unit cardboard carton together with a leaflet.

500 g is packed in a white high density polyethylene jar with a white polypropylene screw cap, together with a leaflet.

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 NUMBERS

CORTODERM OINTMENT: L/13.4.1/29

CORTODERM CREAM: L/13.4.1/42

9. DATE OF FIRST AUTHORISATION

CORTODERM OINTMENT: 24 July 1978

CORTODERM CREAM: 09 August 1978

10. DATE OF REVISION OF TEXT

19 December 2024

Die Afrikaanse Professionele Inligting is op versoek beskikbaar.

Mediese Blitslyn: 0800 118 088.

Botswana:	
CORTODERM OINTMENT:	BOT0801150 S2

Namibia:	NS2
CORTODERM CREAM:	90/13.4.1/00871
CORTODERM OINTMENT:	90/13.4.1/00873

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