1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

DILUCORT CREAM 0,5 g/100 g

DILUCORT OINTMENT 0,5 g/100 g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of DILUCORT CREAM contains 0,5 g hydrocortisone acetate.

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

Each 100 g of DILUCORT OINTMENT contains 0,5 g hydrocortisone acetate.

For full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

DILUCORT CREAM: Cream

DILUCORT OINTMENT: Ointment

DILUCORT CREAM is a smooth white to off-white cream.

DILUCORT OINTMENT is a smooth off-white ointment.

4. CLINICAL PARTICULARS

4.1Therapeutic indications

DILUCORT is indicated for:

- The temporary relief of itching associated with minor skin irritations due to eczema, insect bites, poison plants, soaps, detergents, cosmetics, jewellery, seborrhoeic dermatitis.
- The relief of external genital and anal itching.

Other uses for the medicine should be only under the advice and supervision of a doctor.

4.2. Posology and method of administration

Posology

DILUCORT should be applied to the affected area up to four times a day until improvement occurs, then the frequency of application may be reduced.

DILUCORT should be massaged gently and thoroughly into the skin.

Method of administration

For topical application

Paediatric population

The safety and efficacy of DILUCORT in children under the age of 2 years has not yet been established (see section 4.3).

4.3. Contraindications

DILUCORT is contraindicated in:

- Patients with hypersensitivity to hydrocortisone acetate or to any of the excipients in DILUCORT (see section 6.1).

- The presence of vaginal discharge. Consult a doctor.
- Use for cosmetic purposes.
- Nappy rash.
- The event of external anal itching accompanied by bleeding. Consult a doctor immediately.
- Application into the rectum by using fingers or any mechanical device or applicator.
- Indications pertaining to the genital and anal use in children under the age of 12 years. Consult a doctor.
- Usage for longer than 7 days.
- Use in the presence of skin lesions caused by bacterial (impetigo), fungal (candidiasis, tinea) or viral (e.g. herpes simplex, vaccinia or varicella) infections.
- Rosacea, acne, peri-oral dermatitis, tuberculosis of the skin and varicose ulcers.
- Children under the age of 2 years.
- Use exceeding the recommended dose.
- Use during pregnancy as corticosteroids have been shown to be teratogenic in animals following dermal application. As these medicines are absorbed percutaneously, teratogenicity following topical application cannot be excluded (see section 4.6).

4.4 Special warnings and precautions for use

General topical corticosteroid warnings

DILUCORT should not be used for cosmetic purposes.

For external use only.

Facial dermatoses and atrophic skin changes

DILUCORT should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced. Long-term treatment, with topical corticosteroids should be avoided as far as possible as this may cause atrophic changes in the

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

DILUCORT should be used with caution near the eyes. Contact with the eyes should be avoided.

If the condition worsens, or if symptoms persist for more than 7 days or clears up and occurs again within a few days, stop use of this medicine and consult a doctor.

Systemic absorption

Systemic absorption of topically applied corticosteroids 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.

V*isual disturbance*

Visual disturbance may be reported with systemic and topical corticosteroid, as contained in DILUCORT, 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.

Psoriasis

Topical corticosteroids, as in DILUCORT may be hazardous in psoriasis for reasons including rebound relapses following development tolerance, the risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin; careful patient supervision is important.

Withdrawal syndrome

Long term continuous or inappropriate use of topical steroids, such as DILUCORT, 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.

Secondary microbial infection

If a secondary microbial skin infection is present, suitable concomitant antimicrobial therapy should be instituted. Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents.

Paediatric population

There is no experience with DILUCORT and children under the age of 2 years (see sections 4.2 and 4.3).

DILUCORT should not be used to treat nappy rash (see section 4.3).

Excipients

DILUCORT CREAM contains chlorocresol 0,1 % *m/m* which may cause allergic reactions

Treatment with DILUCORT CREAM should be discontinued if this occurs (see section 6.1)

4.5. Interactions with other medicines and other forms of interaction

Not known.

4.6. Fertility, pregnancy and lactation

The use of DILUCORT is contraindicated in pregnancy (see section 4.3.).

Pregnancy

Corticosteroids have been shown to have teratogenic effects in animals, including cleft palate and intra-uterine growth retardation, following dermal application. As these medicines are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, DILUCORT should not be used during pregnancy (see section 4.3).

Breastfeeding

Safety in lactation has not been established and therefore the use during lactation is not recommended.

DILUCORT should not be applied to the chest area.

Fertility

There are no data available regarding DILUCORT and fertility.

4.7. Effects on ability to drive and use machines

Due to undesirable effects such as blurred vision DILUCORT has minor influence on the ability to drive or operate machinery.

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

4.8. Undesirable effects

a) *Tabulated list of adverse events*

System organ class	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Endocrine disorders		Depression of the hypothalamic-pituitary-adrenal axis, suppression of the adrenal gland, retarded growth, Cushingoid state.
Nervous system disorders	Benign intracranial hypertension	
Eye disorders		Blurred vision
Skin and subcutaneous tissue disorders		atrophic changes in the skin, thinning, loss of elasticity, dilation of superficial blood vessels, telangiectasiae and ecchymoses. 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 Skin pigmentation changes, hypertrichosis

b) *Description of selected adverse reactions*

Treatment with hydrocortisone, as in DILUCORT, is usually well tolerated but treatment should be stopped immediately if symptoms of hypersensitivity occur including allergic contact dermatitis or worsening of the original condition.

Endocrine disorders

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.

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: 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

See section 4.8 undesirable effects.

Acute overdosage is very unlikely to occur. In the case of chronic overdosage or misuse the features or hypercorticism may appear and in this situation topical steroids should be discontinued.

Treatment

Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 13.4.1 Corticosteroid with or without anti-infective agents

Pharmacotherapeutic group: Corticosteroids, weak (group I)

ATC Code: D07AA2

Mechanism of action

Hydrocortisone has anti-inflammatory, anti-pruritic, anti-allergic and vasoconstrictive effects.

5.2 Pharmacokinetic properties

None available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

DILUCORT CREAM: Chlorocresol, emulsifying wax, purified water, yellow soft paraffin

DILUCORT OINTMENT: Paraffin liquid, paraffin soft white

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Dilucort Cream: 24 months

Dilucort Ointment (aluminium tube): 36 months

Dilucort Ointment (polyethylene jar): 24 months

6.4 Special instructions for storage

Store at or below 25 °C in well-closed containers.

Protect from light.

Keep in original packaging until required for use.

6.5 Nature and contents of container

DILUCORT CREAM:

25 g is packed into an epoxy phenolic-lined aluminium tube sealed with a high density polyethylene cap placed in a unit carton together with a leaflet.

400 g is packed into a white, high density polyethylene jar sealed with a high density polyethylene cap and labelled.

DILUCORT OINTMENT:

25 g is packed in an epoxy phenolic-lined aluminium tube sealed with a high density polyethylene cap and placed in a unit carton together with a leaflet.

400 g is packed into a white, high density polyethylene jar sealed with a high-density polyethylene cap and labelled.

Not all packs and 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

DILUCORT CREAM: R/13.4.1/21

DILUCORT OINTMENT: R/13.4.1/20

9. DATE OF FIRST AUTHORISATION

DILUCORT CREAM: 11 September 1985

DILUCORT OINTMENT: 11 September 1985

10. DATE OF REVISION OF TEXT

04 December 2023

Die Afrikaanse Professionele Inligting is op versoek beskikbaar.

Mediese Blitslyn: 0800 118 088.

Namibia:	NS1
DILUCORT CREAM:	90/13.4.1/001617
DILUCORT OINTMENT:	90/13.4.1/001618

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