1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

DILUCORT CREAM

DILUCORT OINTMENT

COMPOSITION

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

Excipients:

Chlorocresol, emulsifying wax, yellow soft paraffin

Preservative:

Chlorocresol 0,1 % *m/m*

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

Excipients:

Paraffin liquid, paraffin soft white

CATEGORY AND CLASS

A 13.4.1 Corticosteroid with or without anti-infective agents

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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

INDICATIONS

For the temporary relief of itching associated with minor skin irritations due to eczema, insect bites, poison plants, soaps, detergents, cosmetics, jewellery, seborrhoeic dermatitis and for the relief of external genital and anal itching. Other uses for the product should be only under the advice and supervision of a doctor.

CONTRAINDICATIONS

Do not use in the presence of vaginal discharge. Consult a doctor.

Do not use this product for cosmetic purposes.

Do not use this product for nappy rash.

In the event of external anal itching accompanied by bleeding consult a doctor immediately. Do not put this product into the rectum by using fingers or any mechanical device or applicator.

This product may not be used for the indications pertaining to the genital and anal use in children under the age of 12 years. Consult a doctor.

Do not use this product for longer than 7 days; do not use in the presence of bacterial, fungal or viral infections; do not use in children under the age of 2 years; do not exceed the recommended dose.

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. Therefore, DILUCORT should not be used during pregnancy (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS

Do not use this product for cosmetic purposes.

For external use only.

Avoid contact with the eyes.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and consult a doctor.

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.

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

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

Topical corticosteroid preparations should be with caution near the eyes.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

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. Therefore, DILUCORT should not be used during pregnancy (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

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

SIDE EFFECTS

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

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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT

See SIDE EFFECTS.

Treatment

Treatment is supportive and symptomatic.

IDENTIFICATION

DILUCORT CREAM: A smooth white cream.

DILUCORT OINTMENT: A smooth off-white ointment.

PRESENTATION

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 are necessarily marketed.

STORAGE INSTRUCTIONS

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

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

DILUCORT CREAM: R/13.4.1/21

DILUCORT OINTMENT: R/13.4.1/20

NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION

Pharmacare Limited

Healthcare Park

Woodlands Drive

Woodmead

2191

DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration:

DILUCORT CREAM: 11 September 1985

DILUCORT OINTMENT: 11 September 1985

Date of the most recent amendment to the professional information as approved by the Authority: 04 October 1993

Namibia:	NS1
DILUCORT CREAM:	90/13.4.1/001617
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