1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DILUCORT CREAM 0,5 g/ 100 g

Hydrocortisone acetate

DILUCORT OINTMENT 0,5 g/ 100 g

Hydrocortisone acetate

Read all of this leaflet carefully because it contains important information for you

DILUCORT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use DILUCORT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DILUCORT with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What DILUCORT is and what it is used for

2. What you need to know before you use DILUCORT

3. How to use DILUCORT

4. Possible side effects

5. How to store DILUCORT

6. Contents of the pack and other information

1. What DILUCORT is and what it is used for

DILUCORT contains a medicine called hydrocortisone. Hydrocortisone acts to temporarily stop itching caused by minor skin irritations caused by:

- Eczema.
- Insect bites.
- Poison plants.
- Soaps, detergents.
- Cosmetics, jewellery.
- Skin condition caused by increased secretion of the sebaceous (oil forming) glands (seborrhoeic dermatitis).
- The relief of external genital and anal itching in patients older than 12 years of age. (see section 2 'Do not use DILUCORT').

2. What you need to know before you use DILUCORT

Do not use DILUCORT:

- If you are hypersensitive (allergic) to hydrocortisone acetate or any of the other ingredients of DILUCORT (listed in section 6).
- In the presence of vaginal discharge.

- For nappy rash.
- For itching on the outside of the genitals and anus that is accompanied by bleeding, consult a doctor.
- Do not put DILUCORT into the rectum by using your fingers, mechanical device or applicator.
- For children under the age of 12 years for indications pertaining to genital and anal use, consult your doctor.
- For longer than 7 days.
- For untreated bacterial, viral or fungal infections.
- For acne, small, inflamed papules or pustules or scaly patches around your mouth (peri-oral dermatitis).
- For cosmetic purposes.
- For facial redness with swollen red bumps and small visible blood vessels (rosacea).
- For tuberculosis (an infectious disease caused by bacteria) of the skin and varicose ulcers (a wound on the leg or ankle caused by abnormal or damaged veins).
- For children under the age of 2 years.
- If you are pregnant or breastfeeding (See section 'Pregnancy and breastfeeding' below).

Warnings and precautions

Take special care with DILUCORT:

- DILUCORT is intended for external use only.
- Stop using DILUCORT and consult your doctor if your condition does not improve within 7 days.

- DILUCORT should be used cautiously in facial diseases of the skin and only for short periods of time (not longer than 7 days). Applying DILUCORT to the face may damage the skin.
- Absorption throughout the body may occur when:
  - large quantities are used.
  - applied to wide areas of the body.
  - applied to damaged skin.
  - a dressing completely covering the wounds is applied.
- DILUCORT should be kept away from the eyes.
- You may experience problems with your vision while using DILUCORT. Consult your doctor.
- If you are treating a condition called psoriasis (skin disease with raised rough scaly areas) DILUCORT may worsen this condition.
- Rebound flares (topical steroid withdrawal syndrome) may occur when stopping treatment with DILUCORT, if used incorrectly (see 'If you stop using DILUCORT').
- If a bacterial/germ infection is present, then a suitable antimicrobial should be used with DILUCORT.

Children

DILUCORT should not be used to treat nappy rash.

DILUCORT should not be used in children younger than 2 years old.

Other medicines and DILUCORT

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Pregnancy and breastfeeding

You should not use DILUCORT if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Because DILUCORT is absorbed through the skin, it can cause abnormalities in your unborn baby.

Breastfeeding

Do not apply DILUCORT to the chest area if you are breastfeeding.

Driving and using machines

DILUCORT can cause blurry vision and could affect your ability to drive or use machinery. You should not drive, use machinery, or perform any tasks that require concentration until you are certain that DILUCORT does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent DILUCORT may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DILUCORT affects you (see section 4 ‘Possible side effects’).

DILUCORT CREAM contains chlorocresol

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

3. How to use DILUCORT

Always use DILUCORT exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor , pharmacist or nurse if you are not sure.

Gently and thoroughly massage DILUCORT into the affected area up to four times a day until the condition improves.

Once there is an improvement you may apply it fewer times a day.

Do not use DILUCORT for longer than 7 days.

If you use more DILUCORT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use DILUCORT

If you forget to apply DILUCORT at the correct time, do so as soon as you remember.

Do not use a double dose to make up for forgotten individual doses.

If you stop using DILUCORT

You may experience a skin irritation with intense redness, stinging and burning that may spread beyond the area being treated (withdrawal syndrome). You should seek advice from your doctor, nurse or pharmacist before you start using DILUCORT again.

4. Possible side effects

DILUCORT can have side effects.

Not all side effects reported for DILUCORT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DILUCORT, please consult your healthcare provider for advice.

If any of the following happens, stop using DILUCORT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DILUCORT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- A build-up of pressure around the brain, or partial loss of vision, headache (benign intracranial hypertension),
- burning, stinging, itching, oozing pimples (pustules) and peeling of the skin that may spread beyond the area being treated (withdrawal syndrome),

- extreme tiredness, weight loss, loss of appetite (adrenal suppression) due to a decrease in the level of the hormone cortisol in your blood (Hypothalamic-pituitary adrenal (HPA) axis suppression),
- moon like face, unusual rapid weight gain around the belly (cushingoid state).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- Delayed weight gain/growth retardation in children,
- blurry vision,
- thinning of the skin,
- loss of elasticity of the skin,
- spider veins (telangiectasia, dilation of superficial blood vessels),
- skin is lighter than usual in deeply pigmented skin (skin pigmentation),
- bruising of the skin (ecchymoses),
- changes in colour of skin (skin pigmentation changes),
- excessive hair growth (hypertrichosis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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

By reporting side effects, you can help provide more information on the safety of DILUCORT.

5. How to store DILUCORT

Store all medicines out of reach of children.

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

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DILUCORT CREAM contains

The active ingredient is 0,5 g of hydrocortisone acetate in each 100 g.

The other ingredients are chlorocresol, emulsifying wax, purified water, yellow soft paraffin.

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

What DILUCORT OINTMENT contains

The active ingredient is 0,5 g of hydrocortisone acetate in each 100 g.

The other ingredients are paraffin liquid, paraffin soft white.

What DILUCORT looks like and contents of the pack

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

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912/+27 (0)11 239-6200

This leaflet was last revised in

04 December 2023

Registration numbers

DILUCORT CREAM: R/13.4.1/21

DILUCORT OINTMENT: R/13.4.1/20

Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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

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