1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

CORTODERM OINTMENT 1,25 mg/5 g

Fluocinolone acetonide

CORTODERM CREAM 1,25 mg/5 g

Fluocinolone acetonide

Read all of this leaflet carefully before you start using CORTODERM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CORTODERM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CORTODERM is and what it is used for
2. What you need to know before you use CORTODERM
3. How to use CORTODERM
4. Possible side effects
5. How to store CORTODERM
6. Contents of the pack and other information

1. What CORTODERM is and what it is used for

CORTODERM belongs to a group of medicines called topical corticosteroids and is used to reduce redness, itching and swelling caused by diseases of the skin (dermatosis) which shows improvement when cortisone medicines are used.

2. What you need to know before you use CORTODERM

Do not use CORTODERM:

- if you are hypersensitive (allergic) to fluocinolone acetonide or any of the other ingredients of CORTODERM (listed in section 6).
- for the treatment of a virus that causes contagious sores, most often around the mouth or on the genitals (herpes simplex, vaccinia or varicella).
- if you are pregnant.
- continuously for a long time if you have diabetes (high blood sugar) or tuberculosis (TB, and infectious disease caused by bacteria).
- on the skin of children under 1 year of age or on young children.

Warnings and precautions

Special care should be taken with CORTODERM:

- if you experience unfavourable reactions, irritation or sensitisation occur you should stop using this medicine and tell your doctor.
- if your condition has resolved and you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using this medicine without consulting your doctor. On recurrence the redness can extend beyond the initial treatment area, and you may experience a burning sensation.

- if you have a skin infection and inflamed skin, the skin infection must be treated with appropriate medicines. If the condition of the infection does not improve then you will need to make an appointment to see your doctor.
- if you have infections and ulcers of the leg as it causes delayed wound healing.
- If you are applying CORTODERM to skin crease areas (areas where lines and wrinkles form).
- if you are applying CORTODERM near the eyes, avoid exposure to the eyes as it may cause problems with your vision.
- if you have psoriasis and are using CORTODERM to treat it, the condition may worsen and form blisters or pimples with pus (generalised pustular psoriasis).

Children

- Do not use on infants (children under 1 year of age) and young children (see Section 2).

Other medicines and CORTODERM

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

Pregnancy, breastfeeding and fertility

You should not use CORTODERM if you are pregnant.

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 taking this medicine.

Driving and using machines

CORTODERM is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that CORTODERM does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent CORTODERM 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 CORTODERM affects you (see section 4).

CORTODERM ointment contains:

Propylene glycol and stearyl alcohol which may cause skin irritation and/or local skin reactions (e.g. contact dermatitis).

CORTODERM cream contains:

Cetyl alcohol, chlorocresol and propylene glycol which may cause local skin reactions (e.g. contact dermatitis), allergic reactions, and/or skin irritation.

3. How to use CORTODERM

Do not share medicines prescribed for you with any other person.

Always use CORTODERM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

CORTODERM OINTMENT: should be gently rubbed onto the affected area two or three times a day.

When an airtight dressing is required, the affected area must first be cleaned well. CORTODERM is then applied and covered with a suitable dressing.

CORTODERM CREAM: should be gently rubbed onto the affected area two or three times a day.

Your doctor will tell you how long your treatment with CORTODERM will last.

If you have the impression that the effect of CORTODERM is too strong or too weak, tell your doctor or pharmacist.

If you use more CORTODERM 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 CORTODERM

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

If you stop using CORTODERM

You may experience withdrawal reactions such as redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation.

4. Possible side effects

CORTODERM can have side effects.

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

If any of the following happens, stop using CORTODERM 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 CORTODERM. 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:

- Headache, ringing of the ears, vision problems and shoulder pain (benign intracranial hypertension),
- a reduced cortisol response, as a result of hypothalamic-pituitary-adrenal (HPA) axis suppression. This can cause a weakened stress response and reduced defence against infection. Low levels of cortisol can increase your risk of frequent — and potentially severe — infections,
- moon like face, unusual rapid weight gain around the belly (cushingoid state),
- delayed growth (growth retardation) in children.

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:

- Reddening of the face with swollen red bumps (rosacea-like dermatitis),
- rash around the mouth with small red pus filled bumps (perioral dermatitis),
- skin is lighter than usual in deeply pigmented skin (hypopigmentation),
- acne,
- skin thinning (atrophic), drying of skin, loss of elasticity, stretch marks,
- excessive hair growth over the body (hypertrichosis), spider veins (telangiectasia), discoloration of the skin resulting from bleeding under the skin (ecchymoses), small purple coloured spots caused by bleeding into the skin (purpura),
- steroid withdrawal reaction may occur on stopping treatment with the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores irritation at the site of application,
- spread of, or worsening, of infections.

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** 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

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

5. How to store CORTODERM

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Store in well closed containers.

Keep in original packing 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 CORTODERM contains

CORTODERM OINTMENT

The active substance is 1,25 mg of fluocinolone acetonide in every 5 g of ointment.

The other ingredients are beeswax white, cholesterol, paraffin white soft, propylene glycol, stearyl alcohol.

CORTODERM CREAM

The active substance is 1,25 mg of fluocinolone acetonide in every 5 g of cream.

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

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

What CORTODERM looks like and contents of the pack

CORTODERM OINTMENT is a soft white translucent 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 is a soft, smooth white 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.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

This leaflet was last revised in

19 December 2024

Registration numbers

CORTODERM OINTMENT: L/13.4.1/29

CORTODERM CREAM: L/13.4.1/42

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

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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