1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DOVATE OINTMENT 2,5 mg/5,0 g

Clobetasol propionate

Read all of this leaflet carefully before you start using DOVATE OINTMENT

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

1. What DOVATE OINTMENT is and what it is used for

DOVATE OINTMENT belongs to a group of medicines called topical corticosteroids and is for short-term use in the treatment of skin problems such as: seborrhoeic dermatitis, atopic dermatitis, lichen chronicus simplex, pruritus ani, psoriasis, later phase of allergic contact

dermatitis, later phase of irritant dermatitis, discoid lupus erythematosus and lichen planus which do not response to treatment with steroids that are less potent.

2. What you need to know before you use DOVATE OINTMENT

Do not use DOVATE OINTMENT:

- If you are hypersensitive (allergic) to clobetasol propionate or any of the other ingredients of DOVATE OINTMENT (listed in section 6).
- if you are hypersensitive (allergic) to other corticosteroids.
- if you currently have bacterial (including tuberculous), fungal or viral infections of the skin.
- if you have ulcerative skin lesions or rosacea (a skin condition affecting the face).
- if you intend to apply it to ulcers of the leg.
- if you have diabetes mellitus or tuberculosis and intend to use this medicine long term.
- if you are pregnant.

Warnings and precautions

Special care should be taken with DOVATE OINTMENT:

- if you experience joint or bone pain, blisters, fever, fatigue and extreme pain especially if you have been using DOVATE OINTMENT for a prolonged time (these may be symptoms of osteonecrosis and/necrotising fasciitis).
- if you experience weight gain, rounding of the face and begin to bruise easily (these may signs of Cushing's syndrome).
- not to be used continuously for long term or inappropriately on large areas of skin and in flexures.
- while using on thin skin areas such as face, damaged skin and near the eyes. If used on the face, treatment should be limited to 5 days.

- if you have a condition called porphyria.
- if you are applying this medicine under an airtight dressing. Clean the areas well before changing the dressing.
- if used for the treatment of psoriasis, the pustular form of the disease may be provoked. Your doctor will want to see you more often.
- if you have an infection of the skin this will need to be treated.
- if you are applying this medicine on the eyelids ensure that it does not enter your eyes. If DOVATE OINTMENT does get into your eyes rinse it with plenty of water and inform your doctor.
- if you experience problems with your vision, tell your doctor immediately so that he/she may refer you to a specialist.
- if your condition has resolved and you experience a recurrence of your condition shortly after stopping treatment, do not restart using this medicine without consulting your doctor. On recurrence, the redness extends beyond the initial treatment area, and you may experience a burning sensation.

Children and adolescents

In infants and children under 12 years of age, long-term use should be avoided where possible.

Children are more likely to experience thinning, bruising and burning of the skin with the use of topical corticosteroids.

Tight-fitting nappies or plastic pants should not be used on an infant being treated in the nappy area, as these act as airtight dressings.

Other medicines and DOVATE OINTMENT

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 DOVATE OINTMENT 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 our doctor, pharmacist or other healthcare provider for advice before using this medicine.

Driving and using machines

DOVATE OINTMENT can cause blurred vision which may influence your ability to drive. Therefore, you should not drive, use machinery or perform any tasks that require concentration until you are certain that DOVATE OINTMENT does not adversely affect your ability to do so safely (see section 4).

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

DOVATE OINTMENT contains propylene glycol and stearyl alcohol.

Propylene glycol and stearyl alcohol may cause skin irritation and/or local skin reactions.

3. How to use DOVATE OINTMENT

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

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

DOVATE OINTMENT should be applied sparingly once or twice daily, to the affected area until improvement occurs.

Your doctor will tell you how long your treatment with DOVATE OINTMENT will last, however, not to be continued for longer than four weeks without the patient being re-evaluated.

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

If you use more DOVATE OINTMENT 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 DOVATE OINTMENT

If you have missed a dose of DOVATE OINTMENT, apply the dose that you have missed as soon as you remember.

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

If you stop using DOVATE OINTMENT

You may experience 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.

4. Possible side effects

DOVATE OINTMENT can have side effects.

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

If any of the following happens, stop using DOVATE OINTMENT 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 DOVATE OINTMENT. 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:

- Moon like face, unusual rapid weight gain around the belly (Cushingoid state),
- blurred, distorted, eye pain, redness of the eye, decreased or loss of vision (chorioretinopathy, glaucoma),
- delayed growth in children,
- a worsened recurrence of your condition shortly after stopping treatment, which causes the skin to burn, sting, itch, peel and/or have oozing pustules (withdrawal syndrome reactions),
- build-up of pressure in the brain which can lead to headache behind the eyes (benign intracranial hypertension).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Itchy skin (pruritus), local skin burning /skin pain.

Less frequent side effects:

- Opportunistic infections,
- delayed weight gain in children, bone strength weakens (osteoporosis), high blood sugar (hyperglycaemia), feeling extreme thirst and more frequent urination (glucosuria),
- high blood pressure (hypertension), increased weight (obesity), dizziness and fatigue (decreased cortisol levels), hair loss (alopecia), hair breaks off easily (trichorrhexis),
- blurred vision and seeing halo around lights (cataract),
- skin thinning (atrophy), stretch marks (striae), spider veins (telangiectasias), skin wrinkling, skin dryness,

- patches of skin that are lighter than surrounding skin (hypopigmentation),
- excessive hair growth over the body (hypertrichosis),
- worsening of skin problems such as dermatitis,
- pustular psoriasis, redness of the skin (erythema), rash (urticaria), acne,
- irritation or pain where the medicine was applied.

Side effects with an unknown frequency:

- Eye pain, excessive tearing, the sensation of a foreign body in the eye (corneal ulcer),
- fragile skin that bruises easily or has a rash of purple spots,
- red rash appearing on the face (rosacea-like dermatitis), red rash appearing around the mouth (perioral dermatitis),
- 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 that feels soft, wet or soggy to the touch (maceration of the skin) and heat rash (miliaria),
- worsening or spreading of local 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 "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: 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 DOVATE OINTMENT.

5. How to store DOVATE OINTMENT

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep tube tightly closed.

Protect from light.

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 DOVATE OINTMENT contains

The active substance is 2,5 mg of clobetasol propionate in each 5,0 g of ointment.

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

What DOVATE OINTMENT looks like and contents of the pack

DOVATE OINTMENT is soft, smooth off-white ointment.

25 g ointment are packed into an aluminium, collapsible tube, externally printed and internally plain, close nozzle fitted with a white self-piercing, high density polyethylene cap, and placed in a unit cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

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Woodmead 2191

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

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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: NS2 04/13.4.1/0021

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