1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DOVATE CREAM 2,5 mg/ 5 g

Clobetasol propionate

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

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

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

DOVATE CREAM belongs to a group of medicines called topical corticosteroids and is used for short term treatment of skin problems such as: seborrhoeic

dermatitis, atopic dermatitis, lichen simplex chronicus, pruritis ani, psoriasis, later phase of allergic contact dermatitis, later phase of irritant dermatitis, discoid lupus erythematosus and lichen planus which do not respond to treatment with steroids that are less potent.

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

Do not use DOVATE CREAM:

- if you are hypersensitive (allergic) to clobetasol propionate or any of the other ingredients of DOVATE CREAM (listed in section 6),
- if you are hypersensitive (allergic) to other corticosteroids,
- if you currently have a bacterial (including tuberculous), fungal or viral infection of the skin,
- if you have ulcers of the 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 CREAM:

- if you experience joint or bone pain, blisters, fever, fatigue and extreme pain especially if you have been using DOVATE CREAM 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 be signs of Cushing's syndrome),

- if you are applying the cream under an airtight dressing, including a child's nappy, these dressings make it easier for the active ingredient to pass through the skin, it is possible to accidentally end up using too much. Airtight dressings increase the risk of infections. Clean these areas well before changing the dressing,
- if you are applying this medicine on thin skin areas such as face, damaged skin and near the eyes,
- if used for the treatment of psoriasis, as it may make the condition worse, and 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 as this will need to be treated,
- if you are applying this medicine on the eyelids ensure that it does not enter your eyes,
- 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, within 2 weeks, 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.
- if you have a condition called porphyria.

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.

Other medicines and DOVATE CREAM

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 CREAM 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.

Driving and using machines

DOVATE CREAM can cause blurred vision which is likely to affect your ability to drive or use machines.

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

DOVATE CREAM contains cetyl alcohol

May cause local skin reactions (e.g. contact dermatitis).

DOVATE CREAM contains chlorocresol

May cause allergic reactions.

3. How to use DOVATE CREAM

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

Always use DOVATE CREAM exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

DOVATE CREAM 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 CREAM will last, however not to be continued for longer than four weeks without your condition being reviewed.

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

If you use more DOVATE CREAM 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 CREAM

If you have missed a dose of DOVATE CREAM, 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 CREAM

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 CREAM can have side effects.

Not all side effects reported for DOVATE CREAM are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using DOVATE CREAM, please consult your healthcare provider for advice.

If any of the following happens, stop using DOVATE CREAM 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 CREAM. 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, 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).

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:

- Skin infections,
- delayed weight gain in children, weakened bone strength (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),
- skin thinning, stretch marks, spider veins (telangiectasias), skin wrinkling, skin dryness,
- patches of skin that are lighter than surrounding skin (hypopigmentation),
- excessive hair growth (hypertrichosis),
- worsening of skin problems such dermatitis,
- pustular psoriasis, redness of the skin (erythema), acne,
- irritation or pain where the medicine was applied.

Side effects with an unknown frequency:

- Worsening or spreading of skin infections,

- fragile skin that bruises easily or has a rash of purple spots (purpura),
- red rash appearing on the face (rosacea-like dermatitis), red rash appearing around the mouth (perioral dermatitis),
- skin that feels soft, wet or soggy to the touch (maceration of the skin) and heat rash (miliaria).

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 CREAM.

5. How to store DOVATE CREAM

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep container tightly closed.

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 DOVATE CREAM contains

The active substance is 0,0025 g of clobetasol propionate in each 5,0 g of cream.

The other ingredients are cetyl alcohol, chlorocresol, citric acid monohydrate (for pH adjustment), disodium hydrogen phosphate (for pH adjustment), eumulgin, glyceryl monostearate self-emulsifying, propylene glycol, purified water, stearyl alcohol.

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

What DOVATE CREAM looks like and contents of the pack

DOVATE CREAM is soft, smooth white cream.

25 g cream packed into a 25 g aluminium, collapsible tube, externally printed and internally plain, close nozzle fitted with a white self-piercing, high density polyethylene cap.

80 g cream packed into an opaque high density polyethylene squat jar with high density polyethylene lid.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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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 04/13.4.1/0069

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