PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CLOBETASOL LOTION SHALINA

Clobetasol propionate USP 0,05 % w/v

Read all of this leaflet carefully before you start using CLOBETASOL LOTION SHALINA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CLOBETASOL LOTION SHALINA 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 **CLOBETASOL LOTION SHALINA** is and what it is used for
2. What you need to know before you use **CLOBETASOL LOTION SHALINA**
3. How to use **CLOBETASOL LOTION SHALINA**
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1. What CLOBETASOL LOTION SHALINA is and what it is used for

CLOBETASOL LOTION SHALINA contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. CLOBETASOL LOTION SHALINA is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:

- Frequently relapsing eczema.
- Psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding

widespread plaque psoriasis.

- Lichen planus, (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs).
- Discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight).
- Dermatitis and other skin conditions that have not responded to milder steroid lotions or ointments.

2. What you need to know before you use CLOBETASOL LOTION SHALINA

Do not use CLOBETASOL LOTION SHALINA:

- If you are hypersensitive (allergic) to clobetasol propionate or any of the other ingredients of CLOBETASOL LOTION SHALINA (listed in section 6).
- To treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin on and around your nose (rosacea)
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around your anus or genitals (penis or vagina)
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - itchy skin which is not inflamed

Do not use if any of the above apply for you. if you are not sure, talk to your doctor or pharmacist before using CLOBETASOL LOTION SHALINA.

- If you have a child under 1 year of age.
- If you are pregnant
- if you currently have bacterial (including tuberculous), fungal or viral infections of the skin.
- if you have diabetes mellitus or tuberculosis and intend to use this medicine long term.

Warnings and precautions

Special care should be taken with CLOBETASOL LOTION SHALINA:

- If you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with CLOBETASOL LOTION SHALINA especially if you have been using CLOBETASOL LOTION SHALINA for a prolonged time or repeatedly.
- If you use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining CLOBETASOL LOTION SHALINA with these medicines may result in serious infections.
- If you have previously had an allergic reaction with another steroid.
- If you are applying the lotion 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 lotion.
- Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- If you are applying the lotion on broken or damaged skin or within skin folds.
- If you are applying to a large surface area.
- If you have psoriasis, your doctor will want to see you more often.
- If you are using CLOBETASOL LOTION SHALINA for a chronic leg ulcer, you may be at increased risk of local allergic reaction or infection.
- If you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the lotion repeatedly enters the eye.
- If you are applying to thin skin such as the face, as CLOBETASOL LOTION SHALINA may cause skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the lotion is applied.
- If you have a condition called porphyria.
- CLOBETASOL LOTION SHALINA may be absorbed through the skin in sufficient amounts to produce systemic effects, the risk associated with systemic absorption is enhanced.
- Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Contact your doctor if you experience blurred vision or other visual disturbances.

If an infection develops during the use of this medicine, talk to your doctor or pharmacist.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Use in children

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child over the age of 1 year should not normally last more than 5 days unless your doctor has told you to use it for longer. Your doctor may want to see the child every week, whilst using the lotion.
- Dressings or bandages should not be used on children where the lotion is applied.

If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the lotion under an airtight dressing. It will only be at night to help the lotion to start working. After a short period of time, you will then apply the lotion as normal.

If you apply CLOBETASOL LOTION SHALINA to your face

You should only apply the lotion to your face if your doctor tells you to. It should be limited to only 5 days as the skin on your face thins easily. Dressings or bandages should not be used on the face where the lotion is applied. **Do not let the lotion get into your eyes.** If it does, wash it out with plenty of water.

Other medicines and CLOBETASOL LOTION SHALINA

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist, especially if you are taking ritonavir and itraconazole medications, (medicine used in HIV/AIDS and treatment of some fungal infections) which may lead to increased blood system exposure.

Driving and using machines

CLOBETASOL LOTION SHALINA 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 CLOBETASOL LOTION SHALINA does not adversely affect your ability to do so safely (see section 4). It is not always possible to predict to what extent CLOBETASOL LOTION SHALINA 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 CLOBETASOL LOTION SHALINA affects you (see section 4).

CLOBETASOL LOTION SHALINA contains propylene glycol and stearyl alcohol. Propylene glycol and stearyl alcohol may cause skin irritation and/or local skin reactions.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before using CLOBETASOL LOTION SHALINA.

If you do use CLOBETASOL LOTION SHALINA when breast-feeding, do not use it on your breast area to ensure that the baby does not accidentally get CLOBETASOL LOTION SHALINA in their mouth.

3. How to use CLOBETASOL LOTION SHALINA

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

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

- You usually apply a thin layer of CLOBETASOL LOTION SHALINA once or twice a day. This may be reduced as your skin begins to get better, or stopped when better. Your doctor may prescribe a weaker steroid for you to use instead.
- If you are also using an emollient (moisturiser), allow time for CLOBETASOL LOTION SHALINA to be absorbed into your skin before applying the emollient.

- This lotion is for use on your skin only.
- Do not use for more than 4 weeks without talking to your doctor. If you need treatment for a long time, your doctor may decide you need to use a milder lotion or ointment.
- If your skin problem worsens or does not improve within 2 to 4 weeks, talk to your doctor.
- The germs that cause infections like the warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.
- If you are applying the lotion on someone else make sure you wash your hands after use or wear disposable plastic gloves.

If you use more CLOBETASOL LOTION SHALINA than you should

If you apply too much or if accidentally swallowed, it could make you or your child ill, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use CLOBETASOL LOTION SHALINA

If you forget to apply your lotion, apply it as soon as you remember. If it is close to the time, you are next meant to apply it, wait until this time. Do not apply double time to make up for forgotten individual doses.

4. Possible side effects

CLOBETASOL LOTION SHALINA can have side effects.

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

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

- Swelling of your 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 allergic reaction to CLOBETASOL LOTION SHALINA. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

Less frequent:

- Increased weight
- Obesity
- Skin dryness
- Hair loss/lack of hair growth/damaged looking hair
- Allergic reaction, irritation and pain at the site of application
- Redness

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

Frequent:

- A feeling of burning, pain, irritation or itching where the lotion is applied

Less frequent:

- Skin atrophy, striae, telangiectasis, skin thinning, skin wrinkling, skin dryness, hypopigmentation, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/dermatitis, general pustular psoriasis, erythema, rash, urticaria, acne.
- You find that your skin problem gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the lotion, have an infection or need other treatment.
- Skin thinning, this may cause stretch marks.
- Blood vessels under the surface of your skin may become more noticeable.

- Moon face, rounding of the face.
- Skin wrinkling.
- Changes to the colour of your skin.
- Increased body hair.
- If you have psoriasis, you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.
- Skin infection.
- In children, there might be delayed weight gain and growth.
- A decrease in the level of the hormone cortisol in the blood.
- Increased levels of sugar in your blood or urine.
- High blood pressure.
- Cloudy lens in the eye (cataract).
- Increased pressure in the eye (glaucoma).
- Vision problems caused by detachment of the retina in the eye (central serous chorioretinopathy).
- Weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition.

Frequency unknown:

- Blurred vision

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

5. How to store CLOBETASOL LOTION SHALINA

- Store at or below 30 °C. Do not freeze.
- Store all medicines out of reach of children.
- Protect form light and moisture.

- Keep the tube in the outer carton until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- There are no special storage instructions for CLOBETASOL LOTION SHALINA.

6. Contents of the pack and other information

What CLOBETASOL LOTION SHALINA contains

- The active substance is clobetasol propionate.
- The other ingredients are citric acid monohydrate, glycerin, methyl hydroxybenzoate 0.100% w/v, propyl hydroxybenzoate0.05% w/v, propylene glycol, sodium citrate and purified water

What CLOBETASOL LOTION SHALINA looks like and contents of the pack

Clear transparent liquid.

Contents of the pack

30 ml of lotion is packed in a white opaque high-density polyethylene (LDPE) or high-density polyethylene (HDPE) temper evident dropper bottle with a translucent LDPE nozzle closed with a white opaque HDPE pilfer proof cap.

Bottle is enclosed in an outer carton until required for use.

Holder of Certificate of Registration

Pharmadyne Healthcare (Pty) Ltd

72 Steel Road, Spartan

Kempton Park

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Access to the corresponding Professional Information

Pharmadyne Healthcare (Pty) Ltd

72 Steel Road, Spartan

Kempton Park

Telephone number: 010 329 0701