PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CLOBETASOL CREAM SHALINA

Clobetasol propionate USP 0,05 % w/w

Read all of this leaflet carefully before you start using CLOBETASOL CREAM 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 CREAM 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 the leaflet

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2. What you need to know before you use **CLOBETASOL CREAM SHALINA**
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1. What CLOBETASOL CREAM SHALINA is and what it is used for

CLOBETASOL CREAM SHALINA contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. CLOBETASOL CREAM 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 creams or ointments.

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

Do not use CLOBETASOL CREAM SHALINA:

- If you are hypersensitive (allergic) to clobetasol propionate or any of the other ingredients of CLOBETASOL CREAM 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
  - widespread plaque psoriasis, except single lesions
  - if you have diabetes mellitus or tuberculosis and intend to use this medicine long term,
  - if you are pregnant.
- 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 CREAM SHALINA.
- If you have a child under 1 year of age.

Warnings and precautions

Special care should be taken with CLOBETASOL CREAM SHALINA

- If you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with CLOBETASOL CREAM SHALINA especially if you have been using CLOBETASOL

CREAM 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 CREAM SHALINA with these medicines may result in serious infections.
- If you have previously had an allergic reaction with another steroids.
- 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 cream.
- Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- If you are applying the cream 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 for a chronic leg ulcer as 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 cream repeatedly enters the eye.
- If you are applying to thin skin such as the face, as CLOBETASOL CREAM 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 cream is applied.

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.

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 CLOBETASOL CREAM 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.

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 CREAM SHALINA.

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

3. How to use CLOBETASOL CREAM SHALINA

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

Always use CLOBETASOL CREAM SHALINA 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.

- You usually apply a thin layer of CLOBETASOL CREAM 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 CREAM SHALINA to be absorbed into your skin before applying the emollient.
- This cream 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 cream 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 cream on someone else, make sure you wash your hands after use or wear disposable plastic gloves.

How to apply the cream

1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much CLOBETASOL CREAM SHALINA to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit.
3. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

If you have psoriasis

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

If you apply CLOBETASOL CREAM SHALINA to your face

You should only apply the cream 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 cream is applied. **Do not let the cream get into your eyes.** If it does, wash it out with plenty of water.

If you use more CLOBETASOL CREAM SHALINA than you should

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

If you forget to use CLOBETASOL CREAM SHALINA

If you forget to apply your cream, 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 CREAM SHALINA can have side effects.

Not all side effects reported for CLOBETASOL CREAM SHALINA are included in this leaflet. Should your

general health worsen or if you experience any untoward effects while using CLOBETASOL CREAM SHALINA, please consult your health care provider for advice.

If any of the following happens, stop using CLOBETASOL CREAM 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 CREAM SHALINA. 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 feeling of burning, pain, irritation or itching where the cream is applied.
- 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 cream, 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
- Blurred vision

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

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
- Acne

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 CREAM SHALINA.

5. How to store CLOBETASOL CREAM SHALINA

- Store at or below 30 °C. Do not freeze.
- Store all medicines out of reach of children.
- Protect from 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 CREAM SHALINA.

6. Contents of the pack and other information

What CLOBETASOL CREAM SHALINA contains

- The active substance is clobetasol propionate.
- The other ingredients are cetomacrogol 1000, cetostearyl alcohol, chlorocresol, methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, sodium dihydrogen phosphate, white soft paraffin and purified water.

What CLOBETASOL CREAM SHALINA looks like and contents of the pack

White, semi-solid cream

Contents of the pack

White semi-solid cream is packed in a white multi-layered based aluminium lami-tube with a cap. The tube is placed in a carton together with a leaflet.

Pack sizes: 15 g and 30 g.

Not all pack sizes may be marketed.

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

Holder of Certificate of Registration

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