

SCHEDULING STATUS: [S4]

GLENCOSOL SHAMPOO (Viscous liquid)

Read all of this leaflet carefully before you use GLENCOSOL SHAMPOO:

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

1. What GLENCOSOL SHAMPOO is and what it is used for

GLENCOSOL SHAMPOO contains the active ingredient clobetasol propionate and belongs to a group of medicines called dermatological preparations. **GLENCOSOL SHAMPOO** is used for the external (topical) management of moderate to severe plaque-type psoriasis in adults. It is only for use on the skin of the head (scalp).

2. What you need to know before you use GLENCOSOL SHAMPOO

Do not use GLENCOSOL SHAMPOO:

- If you are hypersensitive (allergic) or have had a previous allergic reaction to the active ingredient clobetasol propionate or to any of the other ingredients of **GLENCOSOL SHAMPOO** (listed in *section 6*)
- If you want to use **GLENCOSOL SHAMPOO** on skin areas affected by bacterial, viral (varicella, herpes simplex, herpes zoster), fungal or parasitic infections and specific skin diseases (skin tuberculosis, skin disease caused by syphilis)
- If you have acne vulgaris, rosacea or perioral dermatitis
- If you need it for application (use) close to your eyes
- If you have ulcerous wounds on the area to be treated
- **GLENCOSOL SHAMPOO** must not be used for peri-anal and genital pruritis
- If you are younger than 18 years old

Warnings and precautions

Tell your doctor or health care provider before using GLENCOSOL SHAMPOO.

Special care should be taken with **GLENCOSOL SHAMPOO**:

- If your skin condition returns after you stop with the **GLENCOSOL SHAMPOO** treatment
- If you develop tolerance to the treatment (the treatment does not work anymore)
- If your skin loses its normal appearance (atrophy)
- If you develop tiny widened blood vessels causing red threadlike lines under the skin (telangiectasia)
- If you develop symptoms such as severe tiredness (fatigue), weakness, weight loss, nausea, loss of appetite
- If you are/ have been using **GLENCOSOL SHAMPOO** for a long period of time
- If you notice any of the following symptoms: a rounded face, pink or purple stretch marks or a fatty hump between the shoulders, high blood sugar (hyperglycaemia) and glucosuria (glucose in the urine, gaining weight, dehydration)
- If you are using **GLENCOSOL SHAMPOO** on large surface areas for long periods of time or with an occlusive dressing

- If you are using **GLENCOSOL SHAMPOO** on areas other than the scalp (head). The treatment should not be used on certain areas of the body, such as the eyelids, face, groin, axillae and genito-anal regions
- Avoid any contact of **GLENCOSOL SHAMPOO** with the eyes and lips. If **GLENCOSOL SHAMPOO** does enter the eye, the affected eye should be rinsed with copious amounts of water.
- If you have or ever have had liver problems
- If you have high blood sugar (diabetes mellitus)
- If you develop any signs or symptoms of irritation and/ or an allergic reaction
- If you have or develop skin infections
- If you are pregnant or breastfeeding your baby
- If you are younger than 18 years old
- If you are older than 65 years.

Other medicines and GLENCOSOL SHAMPOO

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

Pregnancy, breastfeeding and fertility

Pregnancy:

You should not use **GLENCOSOL SHAMPOO** if you are pregnant. If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor before you take **GLENCOSOL SHAMPOO**.

Breastfeeding:

GLENCOSOL SHAMPOO is present in human breast milk. You must not breastfeed while you are

treated with **GLENCOSOL SHAMPOO**.

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 **GLENCOSOL SHAMPOO**.

Driving and using machines

As a topical medicine (medicine applied to the skin), **GLENCOSOL SHAMPOO** should not affect your ability to drive or use machines.

3. How to use GLENCOSOL SHAMPOO

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

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

GLENCOSOL SHAMPOO is for application to the skin (scalp).

GLENCOSOL SHAMPOO should be applied directly onto the affected areas twice daily. It should be gently lathered onto the scalp until completely absorbed. Hands should be washed carefully after application.

Your doctor will tell you how long your treatment with **GLENCOSOL SHAMPOO** will last. Do not stop early, because this can cause your symptoms to return.

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

If you use more GLENCOSOL SHAMPOO 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.

In cases where **GLENCOSOL SHAMPOO** is accidentally swallowed, a healthcare professional should be consulted immediately.

If you have any further questions on the use of this medicine, ask your doctor.

If you forget to use GLENCOSOL SHAMPOO

If you forgot to use **GLENCOSOL SHAMPOO**, use it as soon as you remember. Do not use more than what you are instructed to make up for forgotten individual doses.

4. Possible side effects

GLENCOSOL SHAMPOO can have side effects.

Not all side effects reported for **GLENCOSOL SHAMPOO** are included in this leaflet.

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

If any of the following happens, stop using **GLENCOSOL SHAMPOO** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (these might all be signs of an allergic reaction)

These are all very serious side effects. If you have them, you may have had a serious reaction to **GLENCOSOL SHAMPOO**. 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 the following:

- Allergic contact dermatitis (a red rash and irritation where the **GLENCOSOL SHAMPOO** came into contact with the skin)
- A secondary infection of the area on which **GLENCOSOL SHAMPOO** was applied
- Opportunistic infections (infections occurring more frequently and are more severe) of the area on which **GLENCOSOL SHAMPOO** was applied

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:

- Stinging and/or burning of the area on which the medicine was applied
- Uncomfortable feeling of the skin area
- Itching or burning of the skin area
- Abnormal appearance of the skin area (atrophy)
- Small red blood vessels under the skin
- Pain and/ or irritation at the site of application
- Headache
- Folliculitis (inflammation of the hair follicles)

Less frequent side effects:

- Dry skin at the site/ area of application
- Hypopigmentation (blotchy or lighter skin patches)
- Inflammatory rash around the mouth
- Heat rash (blocked sweat ducts)
- Swelling
- Acne
- Redness of the skin
- Stretch marks
- Generalised rash and redness of the skin
- Weight gain around the face
- Slow weight gain or delayed growth in children
- Osteoporosis
- Glaucoma (a condition causing high pressure in the eye which leads to vision loss)
- High blood sugar levels

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- Glucose in the urine
 - Cataracts (a dense, cloudy area forming on the lens of the eye)
 - High blood pressure
 - Weight gain
 - Alopecia (excessive hair loss) and thinning of the hair on the scalp
 - Skin thinning and wrinkling
 - Excessive sweating

Side effect with unknown frequency:

- Blurred vision

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

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

5. How to store GLENCOSOL SHAMPOO

Store at or below 25 °C.

Protect from light. Keep the container tightly closed and in the carton until required for use.

Do not refrigerate or freeze.

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 GLENCOSOL SHAMPOO contains

- The active ingredient is clobetasol propionate.
- The other ingredients are polyquaternium-10, purified water, sodium citrate dihydrate, sodium laureth sulfate, ethanol, citric acid, Coco-betaine.

What GLENCOSOL SHAMPOO looks like and contents of the pack

A 118 mL white, opaque, tapered, oval HDPE bottle with flip-top cap.

Each bottle is packed in an outer cardboard carton with a leaflet.

Holder of Certificate of Registration

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