

Applicant/PHCR:	Galderma Laboratories South Africa (Pty) Ltd
Product proprietary name:	Clobex Shampoo
Registration no.:	A40/13.4.1/0035
Dosage form and strength:	Shampoo (0,5 mg/g clobetasol propionate)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Clobex® Shampoo

Clobetasol propionate 0.5 mg/g

Read all of this leaflet carefully before you start using CLOBEX® SHAMPOO.

- 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
- Clobex® 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

1. What CLOBEX® SHAMPOO is and what it is used for
2. What you need to know before you start using CLOBEX® SHAMPOO
3. How to use CLOBEX® SHAMPOO

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4. Possible side effects

5. How to store CLOBEX® SHAMPOO

6. Contents of the pack and other information

1. What CLOBEX® SHAMPOO is and what it is used for

Clobex® Shampoo is a corticosteroid dermatological preparation.

Clobex® Shampoo is used for the topical treatment of moderate to severe scalp psoriasis and to prevent relapse. Scalp psoriasis is caused by the skin cells of your scalp being produced too quickly.

Clobex® Shampoo is used to treat scalp psoriasis of moderate intensity in adults.

2. What you need to know before you start using CLOBEX® SHAMPOO

Do not use CLOBEX® SHAMPOO:

- If you are hypersensitive (allergic) to clobetasol propionate or any of the other ingredients of Clobex® Shampoo (listed in section 6).

If you answer yes to any of these, you must inform your doctor before starting treatment.

- If you are hypersensitive to other corticosteroids.
- If your scalp areas are affected by infections.
- In areas other than the scalp.

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- If you have bacterial, viral, fungal or parasitic skin infections such as cold sores, varicella (chicken pox), herpes zoster (shingles), impetigo (type of rash on the face), ringworm, athletes' foot, thrush, skin tuberculosis or skin disease caused by syphilis.
- If you have ulcerous wounds (weeping wounds) on your scalp.
- Do not apply Clobex® Shampoo in the eyes or on the eyelids (due to the risk of glaucoma which is high pressure in the eyes, and risk of cataract),
- In children under 18 years of age

Warnings and precautions

Talk to your doctor or pharmacist before using Clobex® Shampoo 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 transplant). Combining Clobex® Shampoo with these medicines may result in serious infections.

Take special care with CLOBEX® SHAMPOO:

- If you are using Clobex® Shampoo daily for the treatment of large surface areas of the scalp or long-term continuous therapy the risk of systemic effects is higher.
- When treating the scalp with Clobex® Shampoo you must not cover the area being treated, for example: a shower cap must not be used as it may make the active substance pass through the skin and affect the other parts of the body.

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- If you abruptly discontinue using Clobex[®] Shampoo it can lead to adrenal insufficiency, especially in children. Clobex[®] Shampoo is not recommended for use in children under 18 years of age.
- Avoid contact with the face, eyelids, axillae (armpits), erosive skin (chapped skin) surface and genital regions. Rinse off immediately with water if any product runs from the scalp.
- If Clobex[®] Shampoo does enter the eye, the affected eye should be rinsed with copious amounts of water. If any irritation persists, talk to your doctor.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Talk to your doctor or pharmacist if you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Clobex[®] Shampoo.

Other medicines and CLOBEX[®] SHAMPOO

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, or think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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Pregnancy

Do not use Clobex[®] Shampoo if you are pregnant.

There is no data for the use of Clobex[®] Shampoo in pregnant women.

Breastfeeding

Mothers on Clobex[®] Shampoo should not breastfeed their infants.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with the body's production of corticosteroid or cause other undesirable effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk.

Driving and using machinery

This medicine contains 100 mg alcohol (ethanol) in each gram which is equivalent to 10% w/w.

Due to the short contact time and the low systemic absorption, Clobex[®] Shampoo should not have any influence on the ability to drive and use machines.

3. How to use CLOBEX[®] SHAMPOO

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

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Always use Clobex[®] Shampoo as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Initial treatment

Clobex[®] Shampoo should be applied on dry scalp once daily, massaging the lesions. Then, Clobex[®] Shampoo should be kept in place without covering the scalp for 15 minutes before rinsing with water and/or hair can be washed by using an additional amount of regular shampoo if needed to facilitate washing. Then, hair can be dried as usual. Hands must be washed carefully after each application.

The initial treatment with a once daily application should be limited to 4 weeks. However, if your scalp psoriasis is significantly improved before the end of treatment, or you see no improvement by the end of the 4 week treatment period, please see your doctor.

Maintenance treatment:

As soon as the scalp psoriasis is clear or if you have mild plaque psoriasis after 4 weeks with the once daily initial treatment regimen, Clobex[®] Shampoo should be used twice weekly to control your condition and to prevent a relapse. The effectiveness and safety of a twice weekly maintenance regimen with Clobex[®] Shampoo in preventing scalp psoriasis relapse has not been demonstrated for more than a 6-month period.

Your doctor will tell you how long you need to use Clobex[®] Shampoo. If you have the impression that the effect of Clobex[®] Shampoo is too strong or too weak, tell your doctor or pharmacist.

Shake well before use.

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Do not swallow.

If you use more CLOBEX® SHAMPOO than you should:

This product is for use on the scalp only. Do not swallow it.

In the event of overdosage or misuse, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to use CLOBEX® SHAMPOO:

If you forget to use Clobex® Shampoo do not use a double dose on the next application to make up for a forgotten dose. Go back to your regular schedule. If you miss several doses, tell your doctor.

If you stop using CLOBEX® SHAMPOO:

If you stop using Clobex® Shampoo, please see your doctor. It may be that worsening of the disease occurs when treatment with Clobex® Shampoo is stopped suddenly, especially if it has been used for a long time. Tell your doctor if you observe such a worsening of your scalp psoriasis conditions.

4. Possible side effects

Clobex® Shampoo can have side-effects.

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If signs of any local intolerance appear, such as a burning sensation or redness to the areas that have been treated, Clobex® Shampoo application should be stopped until these signs disappear. If signs of hypersensitivity appear, such as swelling of the eyelids, face or lips, you may be allergic to Clobex® Shampoo and the application should be stopped immediately.

Endocrine disorders (such as adrenal suppression, Cushing's syndrome) have been observed with prolonged use of Clobex® Shampoo, especially when applied on large surface areas. Nonetheless, as Clobex® Shampoo is rinsed, systemic absorption is seldom observed and therefore, this risk of appearance of such an effect is low.

Using large amounts or keeping Clobex® Shampoo on the scalp for longer than 15 minutes or in prolonged treatment with Clobex® Shampoo may cause local atrophic changes, such as thinning, stretch marks, dilation of surface veins, skin redness, bruising, and local allergic reactions.

If you have rosacea (facial erythema associated with flushing of the skin, and possible papulopustules), the application of Clobex® Shampoo on the face may cause your skin condition to worsen.

Application of Clobex® Shampoo on the face may induce perioral dermatitis (spotty red rash around the mouth).

Clobex® Shampoo may cause the following side effects:

Frequent side effects (may affect up to 1 in 10 people):

- Skin burning sensation

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- Inflammation of the hair follicles

Less frequent side effects (may affect up to 1 in 100 people):

- Endocrine disorders (such as adrenal suppression, Cushing syndrome) have been observed with potent topical steroids, especially when applied on large surface areas or used for prolonged periods
- Eye stinging or burning
- Eye irritation
- Ocular tight sensation
- Glaucoma
- Hypersensitivity
- Headache
- Pain of skin
- Skin discomfort
- Itching
- Acne
- Skin oedema
- Telangiectasia (veins under the surface of your skin may becoming more noticeable)
- Psoriasis aggravation

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- Hair loss
- Dryness of the skin
- Urticaria
- Skin atrophy (thinning of your skin)
- Skin irritation
- Skin tightness
- Allergic contact dermatitis
- Erythema
- Rash

Not known (frequency cannot be estimated from the available data):

- Blurred vision

Not all side-effects reported for Clobex[®] Shampoo are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using Clobex[®] Shampoo, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 Clobex® Shampoo.

5. How to store CLOBEX® SHAMPOO

Store all medicines out of reach of children.

Store in a cool place at or below 25 °C.

Do not use after the expiry date stated on the carton.

Discard the bottle 6 months after opening.

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 CLOBEX® SHAMPOO contains

The active substance is clobetasol propionate.

Each gram contains 500 micrograms of the active ingredient clobetasol propionate.

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The other ingredients are citric acid monohydrate, coco-betaine (30 % aqueous solution), ethanol – 96 % (10 % w/w), polyquaternium-10, purified water, sodium citrate and sodium laureth sulphate (70 % aqueous solution).

What CLOBEX® SHAMPOO looks like and contents of the pack

Clobex® Shampoo is a viscous, translucent, colourless to pale yellow liquid shampoo with an alcoholic odour.

Clobex® Shampoo is available in white plastic bottles containing 60 ml or 125 ml of shampoo.

Holder of Certificate of Registration

Galderma Laboratories South Africa (Pty) Ltd

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