Package leaflet: Information for the user

Clobetasol propionate 500 micrograms/g shampoo

(clobetasol propionate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. 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.

This medicine is available as Clobetasol propionate 500 micrograms/g shampoo but will be called clobetasol shampoo throughout the rest of this leaflet.

What is in this leaflet

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

1. What Clobetasol Shampoo is and what it is used for

This medicine belongs to a group of medicines called topical corticosteroids (or steroids). 'Topical' means that it should only be applied to the surface of the skin. Topical steroids reduce the redness, itchiness and inflammation associated with skin conditions.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent, or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Clobetasol propionate is classed as a very strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

Scalp psoriasis is caused by the skin cells of your scalp being produced too quickly. Clobetasol Shampoo is used to treat scalp psoriasis of moderate intensity in adults.

2. What you need to know before you use Clobetasol Shampoo

Do not use this medicine
- If you have been told that you are allergic (hypersensitive) to Clobetasol propionate or any of the other ingredients in this medicine. Please check by reading the list of ingredients listed in section 6 below. If you answer yes, you must inform your doctor before starting treatment.
- 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.
- In children under two years old.
- Do not apply this medicine in the eyes or on eyelids (risk of glaucoma which is high pressure in the eye and risk of cataract which is a clouding of the lens in the eye).

Warnings and precautions
Talk to your doctor or pharmacist before using Clobetasol Shampoo:
- 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 Shampoo with these medicines may result in serious infections.

Take special care with Clobetasol shampoo
- When using Clobetasol shampoo, it must only be used on the scalp, do not use it as a regular shampoo or on other areas of the body and do not use Clobetasol shampoo as a shower gel, body wash or bath foam.
- When treating the scalp with Clobetasol 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.
- When using Clobetasol shampoo, 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 you get Clobetasol shampoo in your eye(s), wash the affected eye thoroughly with water. If any irritation persists, please seek advice from your doctor.
- If you do not notice an improvement of your scalp psoriasis, please see 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 Clobetasol shampoo, especially if you have been using Clobetasol shampoo for a prolonged time or repeatedly.

Children and adolescents
- If this product has been prescribed for a child or adolescent below 18 years of age, you must check with your doctor every week before continuing to use this product.

Other medicines and Clobetasol Shampoo
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
This medicine has no or very little influence on the ability to drive and use machines.

This medicine contains ethanol
This medicine contains 100 mg alcohol (ethanol) in each gram which is equivalent to 10% w/w.
It may cause a burning sensation on damaged skin.

This medicine contains sodium laureth sulfate
Sodium laureth sulfate may cause skin and eye irritation.

3. How to use Clobetasol Shampoo

Always use Clobetasol shampoo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual daily dose per application is an amount equivalent to around a half tablespoon (around 7.5ml) sufficient to cover the entire scalp.

Unless your doctor has instructed otherwise, wash your hands and apply Clobetasol shampoo directly to your dry scalp once daily taking care to well cover and massage the affected areas. Avoid using large amounts of Clobetasol shampoo, only use enough to cover your scalp when dry. Wash your hands carefully after application. Leave the product to work for 15 minutes without covering, and then add water, rinse and dry your hair as usual. Your regular shampoo can be used if more shampoo is required to wash your hair. Do not add more of Clobetasol shampoo to your hair.

Your doctor will tell you how long you need to use Clobetasol shampoo to control your scalp psoriasis. Treatment should not continue for more than 4 weeks. However, if your scalp psoriasis is significantly improved before the end of treatment, please see your doctor. On the contrary, if no improvement is seen by the end of the treatment, please tell your doctor. This treatment needs careful supervision; you should let your doctor review your progress at regular intervals. Do not use Clobetasol shampoo for longer than your doctor tells you.

Nonetheless, your doctor may ask you to use Clobetasol shampoo again in the future following a period of no use.

Use in children and adolescents
If this product has been prescribed for children or adolescents between the ages of 2 and 18 years, the instructions given by your doctor must be followed. You must check with the doctor every week before continuing treatment.

If you use more Clobetasol Shampoo than you should
If you have used Clobetasol shampoo for much longer than you should, please see your doctor. This product is for use on the scalp only. Do not swallow it. If you accidentally do so, small amounts are not harmful. If you are not sure, seek immediate medical advice.

If you forget to use this medicine
If you forget to use Clobetasol 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 have any further questions on the use of this product, ask your doctor or pharmacist.

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Clobetasol shampoo may cause the following side effects.

Common side effect (may affect up to 1 in 10 people):
- Skin burning sensation
- Inflammation of one or more hair follicles

Uncommon 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
- 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

Irritation, itching, urticaria, visible small vessels or thinning skin around the treated areas are generally of a mild to moderate nature.
- If you have any signs of local intolerance, such as a burning sensation or redness to the areas that have been treated, do not use Clobetasol shampoo until these symptoms have disappeared.
- Stop using the medicine and tell your doctor as soon as possible if you find your condition gets worse during treatment (this is more likely to happen if you have been using Clobetasol shampoo longer than prescribed) or if you experience swelling of the eyelids, face or lips as you may be allergic to the product or have a skin infection.
- Using large amounts or keeping the product on the scalp for more than 15 minutes may:
  - cause the skin to become thinner so that it can damage more easily.
  - allow the active substance to pass through the skin; this can affect other parts of the body, especially in children, and during pregnancy.
- Repeated courses of topical steroids over a long time may also sometimes cause, pustular eruptions (big pimples) and changes in hair growth and skin colour. Striae (stretch marks) and purpura (bruising) may become noticeable.
- If you have rosacea (facial erythema associated with flushing of the skin, and possible papulopustules) the application of Clobetasol shampoo on the face may cause your skin condition to worsen.
- Application of Clobetasol shampoo on the face may induce perioral dermatitis (spotty red rash around the mouth).
- Application of Clobetasol shampoo to the skin may cause thinning of skin and therefore it should never be used on the face or on other areas of the skin than the scalp.
- In order to avoid interaction with hair colour dying product, such as hair colour changes, Clobetasol shampoo should be thoroughly rinsed.
- If you have any unusual discomfort that you do not understand, tell your doctor as soon as possible.
- If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Clobetasol Shampoo

Keep out of the sight and reach of children.

Store in the original plastic bottle in order to protect from light. Discard the bottle 6 months after first opening.

Do not use the shampoo after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.

If the shampoo becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Clobetasol shampoo contains
- The active substance is clobetasol propionate. Each gram of shampoo contains 500 micrograms of clobetasol propionate.
- The other ingredients are ethanol 96%, sodium laureth sulfate, coco alkyl dimethyl betaine, polyquaternium 10, citric acid monohydrate, sodium citrate, and purified water.

What Clobetasol shampoo looks like and contents of the pack
Clobetasol 500 micrograms/g shampoo is a viscous, semitransparent, colourless to pale yellow liquid shampoo with an alcoholic odour.
60ml or 125ml of shampoo in high density polyethylene (HDPE) bottles with polypropylene (PP) closure and tamper-proof system in carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Penlan Healthcare Limited
45-47 Monument Hill
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KT13 8RN

Manufacturer
BELUPO lijekovi i kozmetika, d.d.
Danica 5
48 000 Koprivnica
Croatia

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Penlan Pharmaceuticals

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