

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Clobex 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 use Clobex shampoo
3. How to use Clobex shampoo
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 contains the active substance called clobetasol propionate; it 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.

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.

Corticosteroid topical preparations (e.g. shampoo, creams and ointments) come in four different strengths. These are known as mild, moderately potent, potent or very potent.

Clobetasol propionate is classed as a very potent corticosteroid.

2. What you need to know before you use Clobex shampoo

Do not use Clobex shampoo:

- If you are allergic to clobetasol propionate or any of the other ingredients of this medicine (listed in section 6). 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, athlete's 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 Clobex shampoo 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 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 transplantation). Combining Clobex shampoo with these medicines may result in serious infections.

Take special care with Clobex shampoo

- When using Clobex 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 Clobex shampoo as a shower gel, body wash or bath foam.
- 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.
- When using Clobex 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 Clobex 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 Clobex shampoo, especially if you have been using Clobex 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 Clobex shampoo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 this medicine.

Driving and using machines

Clobex shampoo has no or very little influence on the ability to drive and use machines.

Clobex shampoo contains ethanol

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

3. How to use Clobex shampoo

Always use this medicine exactly as your doctor or pharmacist has told you. 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 7.5 ml) sufficient to cover the entire scalp.

Unless your doctor has instructed otherwise, wash your hands and apply Clobex shampoo directly to your dry scalp once daily taking care to well cover and massage the affected areas. Avoid using large amounts of Clobex 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 Clobex shampoo to your hair.

Your doctor will tell you how long you need to use Clobex 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 Clobex shampoo for longer than your doctor tells you.

Nonetheless, your doctor may ask you to use Clobex 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 Clobex shampoo than you should

If you have used Clobex 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 Clobex shampoo

Do not use a double dose 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, 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common: may affect up to 1 in 10 people

- Skin burning sensation
- Inflammation of one or more hair follicles

Uncommon: 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 Clobex 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 Clobex 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:
 - o cause the skin to become thinner so that it can damage more easily
 - o 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 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).
- Application of Clobex 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, Clobex shampoo should be thoroughly rinsed.
- If you have any unusual discomfort that you do not understand, tell your doctor as soon as possible.

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 national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clobex shampoo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

Store in the original plastic bottle in order to protect from light.

Discard the bottle 6 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clobex shampoo contains

- The active substance is clobetasol propionate.
Each gram (millilitre) of Clobex shampoo contains 500 micrograms of the active ingredient Clobetasol propionate.
- The other ingredients are: ethanol, coco alkyl dimethyl betaine, sodium laureth sulfate, polyquaternium-10, sodium citrate, citric acid monohydrate and purified water.

What Clobex shampoo looks like and contents of the pack

Clobex shampoo is a thick, semitransparent liquid shampoo with an alcoholic smell that is colourless to pale yellow in appearance.

Clobex shampoo is available on prescription from your doctor in white high density polyethylene (HDPE) plastic bottles of 60 ml or 125 ml fitted with polypropylene snap closure. The HDPE bottle of 30 ml is fitted with polypropylene screw closure. Bottles contains 30 ml, 60 ml or 125 ml of shampoo (not all pack sizes may be marked).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

United Kingdom (Northern Ireland), Italy, Ireland and Portugal: Etrivex 500 micrograms/g shampoo
France, Belgium, Poland, Spain, Hungary, The Netherlands, Malta, Sweden, Denmark, Austria,
Luxembourg, Iceland, Czech Republic, Norway, Greece, Slovakia and Finland: Clobex 500 micrograms/g shampoo

This leaflet was last revised in 18-Nov-2024

<Detailed information on this medicine is available on the website of {name of Member State Agency (link)}>