Package leaflet: Information for the user

CLARELUX 500 micrograms/g cutaneous foam in pressurised container

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 your 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.

What is in this leaflet:

1. What CLARELUX is and what it is used for

CLARELUX contains the active substance clobetasol propionate which belongs to a group of medicines known as topical corticosteroids. Clobetasol propionate is a very strong topical corticosteroid.

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. CLARELUX 500 micrograms/g cutaneous foam in pressurised container (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.

CLARELUX 500 micrograms/g cutaneous foam in pressurised container is a foam to be applied to the skin.

CLARELUX 500 micrograms/g cutaneous foam in pressurised container is used in adult and adolescent patients from age of 12 years as a short-course treatment of steroid response dermatoses of the scalp such as psoriasis, which do not respond satisfactorily to less active steroids.

2. What you need to know before you use CLARELUX

Do not use CLARELUX:
- If you are allergic to clobetasol propionate, to other corticosteroids or any of the other ingredients of this medicine (listed in section 6).

- If you have an infectious skin disease, either viral (e.g. herpes, shingles, chickenpox…), bacterial (e.g. impetigo …), fungal (caused by microscopic fungi) or parasitic.
- If you suffer from burns, ulcerated lesions or other skin conditions such as rosacea, acne, skin inflammation around the mouth.
- If you have itching (pruritus) around the anus or genitals.
- On any area of your body or face (including the eyelids), apart from your scalp.
- In application to the eyelids (risk of damage to the nerve in the eye (glaucoma) and clouding of the lens (cataract)).
- In infants (children under 2 years old).

Warnings and precautions
Talk to your doctor or pharmacist before using CLARELUX.

Inform your doctor if you previously had an allergy to corticosteroids and/or to any components of this medicine.

Stop treatment immediately and talk to your doctor if there is a worsening of your condition during use – you may be experiencing an allergic reaction, signs of which may include skin rash, itching or painless tissue swelling (oedema), have an infection or your condition requires a different treatment.

Long-term treatment should be avoided.

If you experience a recurrence of your condition shortly (within 2 weeks) after stopping treatment, do not restart using CLARELUX without consulting your doctor unless your doctor has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment, because a rebound phenomenon could be suspected (see section 4).

Due to the deterioration of the skin barrier, there is a risk of sudden onset of painful pustules filled with non-infectious fluid that may be accompanied by fever (generalized pustular psoriasis) or the occurrence of local or systemic toxicity.

Avoid contact with eyes or mucous membranes (nose, mouth).

Do not apply CLARELUX on the eyelids or on the face due to risk of developing cloudy lens in the eyes (cataract) and increased pressure in the eye (glaucoma) which cause irreversible damage to the eyes. Contact your doctor if you experience blurred vision or other visual disturbances.

Wash your hands carefully after each application. Do not touch your eyes until you have washed your hands. In the event of accidental contact with the face or eyes, rinse thoroughly with plenty of water.

Unless supervised by a physician, the application of CLARELUX over a large surface area, or under bandaged and covered areas is to be avoided due to risk of some of the active ingredient passing to the bloodstream. Bacterial infection may occur, facilitated by the heat and moisture in skin under occlusive dressings. Do not use an occlusive dressing, unless directed by your doctor. In this case the skin should be cleaned before each dressing change.

Report any irritation or infection to your doctor as appropriate treatment will need to be used if infection occurs. If the infection spreads, CLARELUX should be discontinued and the infection treated.

As with all topical corticosteroids, CLARELUX can be absorbed through the skin with a risk of the active ingredient passing into the blood stream causing side effects such as the decreased production of adrenal glands hormones (pituitary adrenal system suppression) and Cushing’s syndrome - see Section 4

for all possible side effects. The risk of this corticosteroid passing into the bloodstream is increased in the following situations:

- Long-term treatment;
- Application to a large surface area;
- Application under bandaged or covered areas, such as occlusive dressings;
- Application on broken, damaged skin, such as wounds or open sores (ulcerations);
- Application on thin skin area such as the face;
- Increased skin hydration.

Inform your doctor if:

- You experience newly developed bone pain or worsening of previous bone symptoms during a treatment with CLARELUX, especially if you have been using CLARELUX for a prolonged time or repeatedly.
- 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 CLARELUX with these medicines may result in serious infections.
- Your condition does not improve after 2 weeks of treatment.
- An infection occurs, as this may require discontinuation of treatment with CLARELUX and administration of appropriate antimicrobial therapy.

Children and adolescents
Treatment is not recommended in children less than 12 years old.

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

CLARELUX with food, drink and alcohol
Not applicable.

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

Pregnancy
CLARELUX should not be used during pregnancy unless advised by your doctor.

Breast-feeding
CLARELUX should not be used during breast-feeding unless advised by your doctor.

Driving and using machines
CLARELUX should not affect your ability to drive or operate machines.

Important information about some of the ingredients in CLARELUX
This medicine contains:

- 2145 mg of alcohol (ethanol) in each application, which may cause burning sensation on damaged skin,
- 74 mg of propylene glycol (E 1520) in each application,
- cetyl and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis),
- polysorbate 60 (E 435), which can cause allergic reactions.

3. How to use CLARELUX

WARNINGS:
The canister contains a pressurised, flammable liquid.
Do not use or store near a naked flame, source of ignition, any heat generating material or electrical device in use.
Do not smoke whilst using or holding this can.

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

Use this medication only for the condition for which it was prescribed. CLARELUX must only be applied to the scalp and should not be swallowed.

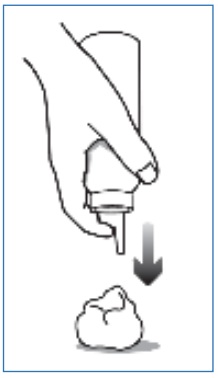
Dispensing directly onto hands is not recommended, as the foam will begin to melt immediately upon contact with warm skin.

Apply CLARELUX to the affected area of the scalp **twice a day, once in the morning and once at night**, as follows:

Attention: for proper dispensing of foam, it is important to hold the container **upside down!**

1. Shake the can well.

2. Turn the can **upside down** and squirt a small amount (the size of a walnut) either directly onto the scalp, or into the cap of the can, onto a saucer or other cool surface and then onto the scalp.
CLARELUX should always be applied thinly, so use as little as possible when covering the affected areas. The exact amount you need depends on the size of the affected area.
Do not squirt CLARELUX onto your hands, as the foam will begin to melt immediately upon contact with warm skin.



3. Move the hair away from the foam and gently massage into the scalp, until it disappears and is absorbed. Repeat if necessary, to treat the entire affected area.

Wash your hands after applying CLARELUX and discard any unused foam.

Do not use CLARELUX on your face or to your eyelids. If some foam accidentally gets into your eyes, nose or mouth, rinse immediately with cold water. You may feel a stinging sensation. Contact your doctor, if the pain continues.

The treated areas should not be bandaged or covered unless directed by your doctor.

Do not wash or rinse the treated scalp areas immediately after applying CLARELUX.

Duration of treatment
Do not use more than 50 g of CLARELUX foam per week.

Treatment should not be given for more than 2 weeks. After this period CLARELUX may be used occasionally if needed. Alternatively, your doctor may prescribe a weaker steroid to control your condition.

If you use more CLARELUX than you should
Inform your doctor immediately if you have applied CLARELUX in quantities larger than the prescribed dose or for a longer period than that stated on your prescription. In these cases, there is a risk of the active ingredient passing into the blood stream causing side effects such as symptoms of hypercorticoidism (weight gain, fat build-up on the face, high blood pressure). The use of CLARELUX should be withdrawn gradually and under medical supervision, by reducing the frequency of application or by substituting to a less potent corticosteroid.

If you forget to use CLARELUX
Use it as soon as you remember, then continue as before. If you only remember at the time of your next dose, use a single dose and continue as before (do not apply a double dose to make up for the forgotten dose). If you miss several doses, tell your doctor.

If you stop using CLARELUX
Do not stop using CLARELUX suddenly as this may harm you. Your doctor may need to discontinue the treatment gradually and you may need regular check-ups.

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.
Stop using CLARELUX 500 micrograms/g cutaneous foam and contact your doctor immediately if

allergic reactions (hypersensitivity) occur, such as local irritation.

The side effects may include:

Common side effects (may affect up to 1 in 10 people but more than 1 in 100):

- Burning sensation of skin where CLARELUX is applied
- Other skin reactions where CLARELUX is applied

Rare effects (may affect up to 1 in 1,000 people):

- Pustular psoriasis (chronic skin inflammation accompanied by pustules)

Very rare effects (may affect up to 1 in 10,000 people):

- Decreased production of adrenal glands hormones (Hypothalamic Pituitary adrenal system suppression)
- Sensation like numbness, tingling or pricking (paraesthesia)
- Eye irritation
- Swollen blood vessels (vasodilation)
- Skin irritation, pain of skin (tenderness), skin tightness
- Itchy skin rash (contact dermatitis), inflammation of the skin (dermatitis)
- Aggravation of psoriasis
- Redness (erythema) at the application site
- Itching (pruritus) at the application site
- Pain
- Presence of blood, protein and nitrogen in your urine may be detected by a doctor
- Alterations in the blood test indicating that red blood cells are larger than average (mean cell volume increased)

Additional side effects may include with an unknown frequency (cannot be estimated from the available data):

- Secondary infection may occur, particularly in the event of treatment covered by an occlusive dressing or in skinfolds (armpits, anal and genital region). Signs of infection include redness of the skin, possibly accompanied by pain or itching.
- Excessive hairiness (hypertrichosis)
- Changes in skin colour
- Inflammation of hair follicles (folliculitis)
- Mouth rashes (perioral dermatitis)
- Redness and eruptions on the face (rosacea-like dermatitis)
- Delay in wound healing
- Cloudy lens on the eyes (cataract), high pressure in the eye (glaucoma)
- Blurred vision

Side effects caused by prolonged use include with an unknown frequency (cannot be estimated from the available data):

- As with other topical corticosteroids, when CLARELUX is used in large amounts and for a long period of time, this can lead to a disorder called Cushing's syndrome which include signs such as weight gain, fat build-up on the face and bruising caused by too much of corticosteroid hormone.

- Topical steroid withdrawal reaction (rebound phenomenon). If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after 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.
- Local changes in the skin such as thinning (skin atrophy) and fragility, colorful bruises (ecchymoses), small visible blood vessels (telangiectasia) especially on the face, stretch marks (striae) particularly affecting the proximal limbs.

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; website: 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 CLARELUX

- **The canister contains a pressurised, flammable liquid.**
- **Do not store near a naked flame, source of ignition, any heat generating material or electrical device in use.**
- **Do not expose to temperatures higher than 50ºC or to direct sunlight.**
- **Do not pierce or burn the can even when empty.**
- **When you have finished your treatment, dispose of the can safely.**

Keep out of the sight and reach of children.

Do not use CLARELUX after the expiry date which is stated on the can and the outer carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate. Store upright.

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 to protect the environment.

6. Contents of the pack and other information

What CLARELUX contains
The active substance is clobetasol propionate and 1 g of cutaneous foam contains 500 micrograms of clobetasol propionate.

The other ingredients are: ethanol anhydrous, purified water, propylene glycol (E 1520), cetyl alcohol,

stearyl alcohol, polysorbate 60 (E 435), citric acid anhydrous, potassium citrate and a propane/*n*-butane/isobutane propellant mixture.

What CLARELUX looks like and contents of the pack
CLARELUX 500 micrograms/g cutaneous foam is a cutaneous white foam in pressurised container.
Each can contains 50 or 100 grams.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pierre Fabre Limited
250 Longwater Avenue
Green Park
Reading RG2 6GP

Manufacturer(s)
Recipharm Uppsala AB
Björkgatan 30
751 82 Uppsala
Sweden

Or

Farmol Health Care S.r.L.
Via del Maglio, 6
23868 Valmadrera (LC), Italy

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