**Package leaflet: Information for the user**

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

CLARELUX 500 microgram/g cutaneous foam in pressurised container is used 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, 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 condition such as rosacea, acne, skin inflammation around the mouth, itching (pruritus) around the anus or genitals.
- On any area of your body or face (included the eyelids), apart from your scalp.
- In children under 2 years old.

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

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.

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.

As with all topical corticosteroids, CLARELUX can be absorbed through the skin and can cause side effects such as adrenocortical suppression - see Section 4 for all possible side effects. Due to this:
- Long-term treatment with CLARELUX should be avoided;
- CLARELUX should not be applied to a large surface area;
- The treated areas should not be bandaged or covered unless directed by your doctor;
- The use of Clarelux on wounds or ulcerations is not recommended.
- Contact your doctor if you experience blurred vision or other visual disturbances.

**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.
- You start to experience problems with your vision, as this type of medicine may increase the development of cataracts and glaucoma.

Wash your hands carefully after each application.
In the event of accidental contact with the face or eyes, rinse thoroughly with plenty of water.

**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.

**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.
CLARELUX should not be used during pregnancy or 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 in each application,
- cetyl and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

## 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 apply to the eyelids and take care to avoid

contact with eyes, nose, and mouth.
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. 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.

Do not use more than 50g 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
- for a longer period than that stated on your prescription.

**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 microgram/g cutaneous foam and contact your doctor immediately if

hypersensitivity reactions 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
- Other skin reaction when applied to the skin

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

- Sensation of tingling or pricking
- Eye irritation
- Swollen veins
- Skin irritation and tenderness
- Skin tightness
- Itchy skin rash (contact dermatitis)
- Aggravated scaly skin rash (psoriasis aggravated)
- Redness at the application site
- Itching and sometimes with pain at the application site
- Presence of blood, protein and nitrogen in your urine may be detected by a doctor

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

- Changes in hair growth (abnormal hair growth away from the application site and on unusual parts of the body)
- Changes in skin colour
- Irritation of the hair follicules e.g. pain, heat and redness
- Mouth rashes
- Redness and eruptions on the face
- Delay in wound healing
- Effects on the eyes (cataract, high pressure in the eye)
- Blurred vision

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

- White markings on skin (striae) and dilatation of the blood vessels of the skin
- 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 symptoms include a red, puffy and rounded face (called a moon face), high blood pressure, weight gain and changes in sugar levels in the blood and urine.
- Prolonged treatment with steroids may cause thinning of the skin.
- 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.

In rare instances, treatment of psoriasis with corticosteroids (or on stopping treatment) may make the condition worse and a pustular form of the disease may occur. On stopping treatment with corticosteroids, sometimes, the scalp condition may return. Also pre-existing infections may worsen if CLARELUX is not used according to the instructions.

**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: https://yellowcard.mhra.gov.uk 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, cetyl alcohol, stearyl alcohol, polysorbate 60, citric acid anhydrous, potassium citrate and a propane/*n*-butane/isobutane propellant mixture.

**What CLARELUX looks like and contents of the pack**
CLARELUX 500 microgram/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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