Package leaflet: Information for the patient

Aklief 50 microgram/g cream
trifarotene

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 Aklief is and what it is used for

Aklief contains the active substance trifarotene that belongs to a group of medicines called retinoids.
Aklief is used for the cutaneous treatment of *Acne Vulgaris* of the face and/or the trunk in patients from 12 years of age and older, when many comedones (whiteheads and blackheads), papules and pustules (inflammatory pimples) are present.

2 What you need to know before you use Aklief

Do not use Aklief:
- If you are a woman planning pregnancy or if you are pregnant (see section "Pregnancy and breast-feeding")
- If you are allergic to trifarotene or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
- Redness, peeling, dryness, and stinging/burning may be experienced with the use of Aklief cream (see section 4 "Possible side effects"). Talk to a doctor if you experience these symptoms. You are recommended to apply a moisturizer from the initiation of treatment, which may help prevent such reactions. If symptoms do occur the doctor may instruct you to start using a moisturizer (if you have not already), to use the cream less often or to stop for a short time. If the symptoms persist, despite these measures, you may be asked to stop the cream altogether.

- Aklief should not be used on cuts, scrapes, abraded or eczematous skin.
- Aklief should not come into contact with the eyes, eyelids, lips, or mucous membranes. If the product accidentaly enters the eye, wash immediately and abundantly with luke warm water. Be careful when applying to sensitive areas of the skin such as the neck or armpits.
- Caution should be exercised when Aklief cream is applied at the same time as other preparation used on the skin including cosmetics (see also section "Other medicines and Aklief")
- You should not use "waxing" as a depilatory method on skin treated with Aklief.
- If a reaction suggesting sensitivity to any component of the formula occurs, the use of Aklief should be discontinued
- Aklief should not be used on sunburned skin. Excessive exposure to sunlight, including sunlamps or phototherapy should be avoided during the treatment. Use of sunscreen with Sun Protection Factor (SPF) of at least 30 and protective clothing (such as a hat and a shirt) over treated areas is recommended when exposure cannot be avoided. If nevertheless your face, chest, shoulders or back become sunburned, stop medication on the affected area until your skin is healed.

Other medicines and Aklief
Tell your doctor if you are using, have recently used or might use any other medicines.
Caution should be exercised if cosmetics or acne medications with peeling, irritant or drying effects are used, as they may produce additive irritant effects with the medicinal product. If your skin becomes irritated, contact your doctor.

Pregnancy and breast-feeding

Pregnancy
DO NOT use Aklief if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.
If you discover you are pregnant during treatment, stop application of this medicine and consult a doctor immediately.

Breast-feeding
When using Aklief there is a risk that the active substance in cream passes into your breast milk and a risk to the newborn/infant cannot be excluded. You and your doctor must make a decision whether to discontinue breast-feeding or to abstain from Aklief therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the mother.

To avoid the risk of ingestion by, and/or contact exposure of, an infant, nursing women should not apply Aklief to the chest or breast area.

Driving and using machines
Aklief has no or negligible influence on the ability to drive and use machines.

Aklief contains propylene glycol (E1520) which may cause skin irritation.
This medicine also contains 50 mg alcohol (ethanol) in each gram which is equivalent to 5% w/w. It may cause burning sensation on damaged skin.

3. How to use Aklief

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

Important: Aklief is intended for patients from 12 years of age and older only for use on the skin of the face and/or the trunk. Do not use this medicine on any other parts of your body. Do not swallow.

Keep Aklief away from children.

Method of administration

- Before using the pump for the first time, prime it by pressing down several times until a small amount of medicine is dispensed (up to 10 times maximum). The pump is now ready to use. Apply a thin layer of Aklief cream to the affected areas of the face (forehead, nose, chin and right and left cheeks) and all affected areas of the trunk **once a day, in the evening**, on a clean and dry skin:
  - One (1) pump actuation should be enough to cover the face (i.e. forehead, cheeks, nose and chin).
  - Two (2) pump actuations should be enough to cover the upper trunk (i.e. reachable upper back, shoulders and chest). One (1) additional pump actuation may be used for middle and lower back if acne is present.
  - More than four (4) pump actuations in one day is not recommended.
- Avoid contact with the eyes, eyelids, lips and mucous membranes such as inside the nose or the mouth. If you accidentally get cream in any of these areas wash them immediately with plenty of luke warm water.
- Wash your hands immediately after applying the cream.

You are recommended to use a moisturizer as frequently as needed from the initiation of the Aklief treatment. The moisturizer can either be applied before or after Aklief, allowing sufficient time to let the skin to dry between the moisturizer and Aklief application.

Your doctor will tell you how long you will need to use Aklief. After three months of treatment your doctor may need to assess the continued improvement of your acne.

Use in children
Aklief should not be used by children below 12 years of age.

If you use more Aklief than you should
If you use more Aklief than you should on your skin, you will not get rid of your acne any quicker, but your skin may become irritated, scaly and red. Talk to the doctor if you have used more Aklief than you should.
Contact a doctor or the national poison centre immediately if:

- a child has accidentally used this medicine
- you or someone else accidentally swallow this medicine.

Your doctor will advise you on what action needs to be taken.

If you forget to use Aklief
If you forget to use Aklief in the evening, use it the next evening. Do not apply a double dose to make up for a forgotten dose.

If you stop using Aklief
The spots (whiteheads,blackheads and inflammatory pimples) will be reduced only after several applications of this medicine. It is important that you continue using Aklief as long as prescribed by your doctor.
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.

Application site reactions such as redness, peeling, dryness, and stinging/burning of the skin may often be experienced with the use of Aklief cream. See section 2 “Warnings and precautions” for information on what to do if you experience such symptoms.

Aklief may cause the following side effects:

Common side effect (may affect up to 1 in 10 people):

- Application site irritation, pruritus (itch), sunburn.

Uncommon side effect (may affect up to 1 in 100 people):

- Pain of the skin
- Dry skin
- Discolouration (loss of skin pigmentation)
- Erosion (skin loss)
- Rash
- Swelling
- Skin irritation
- Acne
- Dermatitis allergic (skin allergy)
- Erythema (redness)

Rare side effect (may affect up to 1 in 1000 people):

- Urticaria (hives)
- Vesicles
- Eczema “asteatotic” (dry skin with scales and fissures)
- Seborrheic dermatitis (red, scaly and itchy skin)
- Skin burning sensation
- Skin fissures
- Skin hyperpigmentation (darkening of skin pigmentation)
- Eyelid exfoliation (peeling of the eyelid skin) or oedema (swelling of the eyelid skin)
- Chapped lips
- Flushing (red face)

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Aklief

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 carton and tube/pump after

EXP. The expiry date refers to the last day of that month.
Discard the tube or pump 6 months after first opening.

This medicinal product does not require any special storage condition.

Do not throw away unused Aklief cream 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 Aklief contains
- The active substance is trifarotene, one gram of cream contains 50 micrograms of trifarotene.
- The other excipients are allantoin, Simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate), cyclomethicone, ethanol, phenoxyethanol, propylene glycol (E1520), triglycerides medium-chain and purified water.

What Aklief looks like and contents of the pack
Aklief is a white and homogenous cream.
Aklief is available in tube containing 5 grams of cream or pump of 15, 30 or 75 grams of cream.
Pack sizes of 1 tube or 1 pump.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Galderma International,
Tour Europlaza,
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CEDEX,
France

Manufacturer
Laboratoires Galderma
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or
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Toulouser Allee 23a
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Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, United Kingdom (Northern Ireland) and Sweden: Aklief
Cyprus, Germany, Greece and Italy: Selgamis

This leaflet was last revised in August 2022

Detailed information on this medicine is available on the web site of:
HPRA