

# Aklief 50 microgram/g cream

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details. [Include if applicable]

### 1. Why am I using Aklief?

Aklief contains the active substance trifarotene that belongs to a group of medicines called retinoids. Aklief is used for the skin treatment of Acne Vulgaris of the face and/or the trunk in patients from 12 years of age and older.

For more information, see Section [1. Why am I using Aklief?](#) in the full CMI.

### 2. What should I know before I use Aklief?

Do not use if you have ever had an allergic reaction to trifarotene or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Aklief?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Aklief and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Aklief?

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.

More instructions can be found in Section [4. How do I use Aklief?](#) in the full CMI.

### 5. What should I know while using Aklief?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor or pharmacist you visit that you are using Aklief.</li><li>The spots (whiteheads, blackheads and inflammatory pimples) will be reduced only after several application of this medicine. It is important that you continue using Aklief as long as prescribed by your doctor.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Aklief should not be applied at the same time as other beauty treatment in which hairs are removed.</li></ul>
<b>Driving or using machines</b>	No or negligible influence on the ability to drive and use machines.
<b>Drinking alcohol</b>	Not applicable
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Aklief does not require any special storage condition.</li></ul>

For more information, see Section [5. What should I know while using Aklief?](#) in the full CMI.

### 6. Are there any side effects?

Irritation of the skin, pruritus (itch), sunburn are the common side effects with Aklief.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at

[www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Aklief 50 microgram/g cream

Active ingredient: Trifarotene

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Aklief to the patient or the carer. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Aklief.**

### Where to find information in this leaflet:

1. [Why am I using Aklief?](#)
2. [What should I know before I use Aklief?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Aklief?](#)
5. [What should I know while using Aklief?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using Aklief?

Aklief contains the active substance trifarotene that belongs to a group of medicines called retinoids.

Aklief is used for the skin 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/or pustules (inflammatory pimples) are present.

## 2. What should I know before I use Aklief?

### Warnings

#### Do not use Aklief if:

- you are allergic to trifarotene, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- you are a woman planning pregnancy or if you are pregnant (see section “Pregnancy and breast-feeding”)
- you have cuts, scrapes, abraded, eczematous or sunburnt skin.

#### Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

Aklief should not be applied at the same time as other beauty treatment in which hairs are removed (see also section “Other medicines and Trifarotene”).

Redness, peeling, dryness, and stinging/burning may be experienced with the use of Aklief cream (see section 4 “Possible side effects”). You may be asked to apply a moisturiser, to use the cream less often or to stop for a short time or to stop the cream altogether.

Aklief should not come into contact with the eyes, eyelids, lips, or mucous membranes. If the product accidentally enters the eye, wash immediately and abundantly with lukewarm water. Be careful when applying to sensitive areas of the skin such as the neck or armpits.

Aklief should not be used on sunburnt skin. Minimise exposure to sunlight. 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 sunburnt, stop medication on the affected area until your skin is healed.

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”)

If a reaction suggesting sensitivity to any component of the formula occurs, the use of Aklief should be discontinued.

This product contains propylene glycol (E1520) that may cause skin irritation. It also contains alcohol (ethanol) which may cause a burning sensation on damaged skin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

DO NOT use Aklief if you are pregnant or intend to become pregnant. Talk to your doctor about a time period after which pregnancy can be planned after stopping the use of Aklief.

If you discover you are pregnant during treatment, stop application of this medicine and consult a doctor immediately.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

When using Akliel 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 Akliel 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 Akliel to the chest or breast area.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Akliel and affect how it works.**

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Akliel.**

### 4. How do I use Akliel?

#### How much to take / use

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

**Important:** Akliel 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 Akliel away from children.

#### How to apply Akliel

- 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 Akliel 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 pump actuation should be enough to cover the face (i.e. forehead, cheeks, nose and chin).
  - Two pump actuations should be enough to cover the upper trunk (i.e. reachable upper back, shoulders and chest). One additional pump actuation may be used for middle and lower back if acne is present.
- 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 it immediately with plenty of lukewarm water.
  - Wash your hands immediately after applying the cream.

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

Your doctor will tell you how long you will need to use Akliel. The duration of treatment can vary from person to person and depends on the severity of the skin disorder and the results of the treatment. After three months of treatment your doctor may need to assess the continued improvement of your acne.

#### Use in children

Akliel should not be used by children below 12 years of age.

#### If you forget to use Akliel

Akliel should be used regularly at the same time each day. If you miss your dose at the evening, use it the next evening.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

#### If you use too much Akliel

If you use too much Akliel you will not get rid of your acne any quicker, but your skin may become irritated, scaly and red.

If you think that you have used too much Akliel, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using

## Aklief?

Remind any doctor or pharmacist you visit that you are using Aklief.

### Things you should not do

- Do not stop using this medicine suddenly.
  - The spots (whiteheads, blackheads and inflammatory pimples) will be reduced only after weeks of application 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.

### Driving or using machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

### Looking after your medicine

Keep Aklief in a cool, dry place, where the temperature stays below 25°C. **Keep it where young children cannot reach it.**

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.

### When to discard your medicine

Discard the tube or pump 6 months after first opening.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><i>Common Side effects:</i></p> <ul style="list-style-type: none"><li>• Application site Irritation, pruritus (itch), sunburn.</li></ul> <p><i>Uncommon Side effects:</i></p> <ul style="list-style-type: none"><li>• Pain of the skin</li><li>• Dry skin</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and</b></p>

<ul style="list-style-type: none"><li>• Discolouration (loss of skin pigmentation)</li><li>• Erosion (skin loss)</li><li>• Rash</li><li>• Swelling</li><li>• Skin irritation</li><li>• Acne</li><li>• Dermatitis allergic (skin allergy)</li><li>• Erythema (redness)</li></ul> <p><i>Rare Side effects:</i></p> <ul style="list-style-type: none"><li>• Urticaria (hives)</li><li>• Vesicles</li><li>• Eczema "asteatotic" (dry skin with scales and fissures)</li><li>• Seborrheic dermatitis (red, scaly and itchy skin)</li><li>• Skin burning sensation</li><li>• Skin fissures</li><li>• Skin hyperpigmentation (darkening of skin pigmentation)</li><li>• Eyelid exfoliation (peeling of the eyelid skin) or oedema (swelling of the eyelid skin)</li><li>• Chapped lips</li><li>• Flushing (red face)</li></ul>	<p><b>they worry you.</b></p>
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Aklief contains

Active ingredient	Trifarotene (one gram of cream contains 50 micrograms of trifarotene)
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Other ingredients	<ul style="list-style-type: none"><li>• Allantoin</li><li>• Simulgel 600 PHA (acrylamide/sodium acryloyldimethyltaurate copolymer, isohexadecane, polysorbate 80, sorbitan oleate)</li><li>• Cyclomethicone</li><li>• Ethanol</li><li>• Phenoxyethanol</li><li>• Propylene glycol</li><li>• Medium chain triglycerides</li><li>• Purified water</li></ul>
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Do not take this medicine if you are allergic to any of these ingredients.

What Aklief looks like

Aklief is a white and smooth 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.

Who distributes Aklief

Sponsor

Galderma Australia Pty Ltd  
Level 18, 1 Denison Street  
North Sydney NSW 2060  
Ph 1800 800 765.

Australian Registration Number:

AUST R 332220  
AUST R 340375

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