

▼ 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.

Aklief 50 microgram/g cream

Trifarotene

Consumer Medicine Information

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and Aklief 50 microgram/g cream 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 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.

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 Aklief 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 Aklief.