Applicant: Galderma Laboratories South Africa (Pty) Ltd
Product name: Aklief
Dosage form: Cream
Strength:50 µg Trifarotene per 1 g of cream
Registration number: 56/13.12/1007

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

Aklief 50 microgram/g cream

Trifarotene

Read all of this leaflet carefully before you start using Aklief 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, pharmacist, nurse or other health care provider.
- Aklief has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 allergic to trifarotene or any of the other ingredients of this medicine (listed in section 6)
- If you are a woman planning pregnancy or if you are pregnant (see section “Pregnancy and breastfeeding”)

Warnings and precautions

Take special care with Aklief:

Talk to your doctor or health care provider before using Aklief.

- Redness, peeling, dryness, and stinging/burning may be experienced with the use of Aklief (see section 4 “Possible side effects”). Talk to a doctor if you experience these symptoms. You are recommended to apply a moisturiser from the initiation of treatment, which may help prevent such reactions. If symptoms do occur the doctor may instruct you to start using a moisturiser (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 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.

- 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

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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 medicine. If your skin becomes irritated, contact your doctor.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

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

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. Talk to your doctor before using Aklief if you are breastfeeding.

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 cream has no or negligible influence on the ability to drive and use machines.

Aklief contains:

- Propylene glycol which may cause skin irritation.
- Aklief cream 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

Do not share medicines prescribed for you with any other person.

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.

- 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 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 Aklief treatment. The moisturiser can either be applied before or after Aklief, allowing sufficient time to let the skin to dry between the moisturiser 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 and adolescents

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

If you use more Aklief than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

Do not use a double dose to make up for a forgotten dose.

If you forget to use Aklief in the evening, use it the next evening.

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

Aklief can have side effects.

Not all side effects reported for Aklief are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Aklief, please consult your health care provider for advice.

If any of the following happens, stop using Aklief and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- severe rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to Aklief. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

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

Less frequent side effects:

- 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)
- 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)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side affects you can help provide more information on the safety of Aklief.

5. How to store Aklief

Store all medicines out of reach of children.

Store at or below 25 °C. This medicine does not require any special storage conditions.

After first opening of the tube, use the product within 6 months. Discard the tube or pump 6 months after first opening.

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.

Do not throw away unused Aklief cream via wastewater or household waste. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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 ingredients 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.

Holder of Certificate of Registration

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