

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (MEDICINAL PRODUCTS) – 1986**

This medicine is dispensed with a doctor's prescription only

**AKLIEF  
Cream**

**Active ingredient:**

Aklief contains 0.005% w/w of Trifarotene.

One (1) gram of Aklief contains 50 micrograms of Trifarotene.

For information on the inactive ingredients and allergens in the medicinal product, see section 6 'Additional information'.

See also section 2 'Important information on some of the ingredients of the medicine'.

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if seems to you that their medical condition is similar.

**1. WHAT THE MEDICINE IS USED FOR?**

Aklief is indicated 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, papules and pustules are present.

**Therapeutic group:** Retinoids for topical use in acne.

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

**2. BEFORE YOU USE THE MEDICINE**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to active ingredient or any of the other ingredients of this medicine (listed in section 6 'Additional information').
- You are a woman planning pregnancy or if you are pregnant (see section 2 'Pregnancy and breast-feeding').

**Special warnings related to the use of the medicine**

- Redness, peeling of the skin, dryness, and stinging/burning may be experienced with the use of Aklief cream (see section 4 '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 using), to use Aklief less often or to stop

for a short time. If the symptoms persist, despite these measures, you may be asked to stop using Aklief 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 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 is applied at the same time as other preparation used on the skin, including cosmetics (see also 'Drug Interactions/Adverse Reactions' later in this section.).
- 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 using the medication on the affected area until your skin is healed.

### **Elderly patients**

The safety and efficacy of Aklief in patients aged 65 years and above have not been established.

### **Patients with renal and hepatic impairment**

Aklief has not been studied in patients with renal and hepatic impairment.

### **Children and adolescents**

The medicine is not intended to be used in children and adolescents below 12 years of age. The safety and efficacy of Aklief in children below 12 years old have not been established.

### **Drug interactions**

**If you are taking, or have recently taken, or may use any other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

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 the cream passes into your breast milk. 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 to your child and the benefit of therapy for the mother.

## **Driving and using machines**

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

## **Important information on some of the ingredients of the medicine**

This medicine contains 300 mg propylene glycol in each gram which is equivalent to 30% w/w. It 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 THE MEDICINE**

Always use this medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.

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.

The dosage and treatment regimen will be determined by the doctor only.

**The recommended dose is generally:** once a day application. Refer to the instruction below in section 'instructions for use'.

### **Instructions for use**

- 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.

#### **Duration of treatment**

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

#### **Do not exceed the recommended dose**

For external use only. Do not swallow.

**Aklief is intended for application on the skin once daily only. If you have used more Aklief than you should on your skin,** you will not achieve the desired treatment outcome faster, but your skin may become irritated, scaly and red. Talk to your doctor if you have used more Aklief than you should. In such a case, you may need to discontinue the treatment until the skin heals.

**If an adult or child accidentally ingested the medication, or if a child used the product,** refer to the doctor or a hospital emergency room immediately and bring the medicine package with you. The treatment in case of ingestion will be based on the symptoms that appear.

Chronic ingestion of the medicine will likely lead to side effects associated with an overdose resulting from oral intake of Vitamin A.

#### **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.

Adhere to the treatment as recommended by the doctor.

#### **If you stop using Aklief**

The lesions (whiteheads, blackheads and pustular 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.

Before discontinuing treatment consult your doctor or pharmacist.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, the use of Akliel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Talk to a doctor if you experience** application site reactions such as redness, peeling of the skin, dryness, and stinging/burning of the skin that may often be experienced with the use of Akliel. The doctor may instruct you to start using a moisturizer (if you have not already using), 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. See Section 2: "Special warnings related to the use of the medicine".

*Common side effects (may affect up to 1 in 10 users):*

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

*Uncommon side effects (may affect up to 1 in 100 users):*

- 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 effects (may affect up to 1 in 1000 users):*

- Urticaria (hives)
- Vesicles
- Dry skin with scales and fissures (Eczema "asteatotic")
- 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 a side effect appears, if one of the side effects worsens, or you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "[Report Side Effects of Drug Treatment](#)" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

## **5. HOW TO STORE THE MEDICINE?**

- Prevent poisoning! This medicine and any other medicine should be stored in a closed place out of the reach and sight of children and/or infants, thus preventing poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a temperature below 25°C.
- After the first opening, the cream may be used for 6 months, but no later than the expiry date stamped on the package.
- Do not throw away unused Akliel cream via wastewater or household waste. Ask your pharmacist how to throw away unused medicines. These measures will help protect the environment.

## **6. ADDITIONAL INFORMATION**

In addition to the active ingredient, the medicine also contains:

Propylene glycol, medium-chain triglycerides, ethanol (96%), copolymer of acrylamide and sodium acryloyldimethyltaurate (40% dispersion), cyclomethicone 5, phenoxyethanol, allantoin, purified water.

### **What the medicine looks like and the contents of the package**

Akliel is a white and homogenous cream.

Akliel is available in a pump of 15, 30, or 75 grams of cream.

Each package contains one pump. Not all pack sizes may be marketed.

### **Registration holder:**

A.M.I. Medical Technologies Limited, Hanagar 22, Hod-Hasharon, 4501317, Israel .

### **Manufacturer:**

Laboratories Galderma, Z.I. Montdesir 74540, Alby-sur-Chéran, France .

### **Medicine registration number in the National Medicines Registry of the Ministry of Health:**

176-48-37123-99

For simplicity and ease of reading, this leaflet is written in masculine form. However, the medication is intended for both genders.

This leaflet has been checked and approved by the Ministry of Health in May 2024