

# DON'T LET THEIR ACNE BE THE FOCUS



AKLIEF® (Trifarotene 50 mcg/g) cream is indicated for the topical treatment of *acne vulgaris* of the face and/or trunk in patients 12 years of age and older.

**DIN:** 02494175  
**Code:** 052179  
**Size:** 75 g  
**Case:** 24  
**UPC:** 7 72618 06200 7



Wholesaler	Order Code
McKesson	147313
Kohl & Frisch	162591
SDM/Pharmaprix	772618062007
Lawtons, Sobeys, Rexall, Pharma Plus	147313
Familiprix	127031
Jean Coutu	757073
McMahon	10113154

Consult the Product Monograph at <http://ncs.galderma.accsitefactory.com/sites/g/files/jcdfhc196/files/inline-files/Aklief%20PM-E-Nov-25.pdf> for important information on contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling us at 1-800-467-2081.

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 Galderma Canada Inc. Thornhill, Ontario  
 23501219-E

Read this carefully before you start taking AKLIEF and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment, and ask if there is any new information about AKLIEF.

## ABOUT THIS MEDICATION

### **What is AKLIEF used for?**

AKLIEF is used to treat *acne vulgaris* on the face and trunk (upper, middle, and lower back, shoulders, and chest) for patients 12 years and older. *Acne vulgaris* is a skin condition that is caused when your hair follicles become plugged and inflamed. This causes your skin to break out with pimples, blackheads, or whiteheads.

### **How does AKLIEF work?**

AKLIEF contains trifarotene which belongs to a group of medicines called retinoids. AKLIEF works by unplugging your blocked hair follicles and by preventing these plugs from forming in the first place. Your acne should improve in 4–8 weeks and you should see more improvement as you continue to use AKLIEF.

### **What are the ingredients in AKLIEF?**

Medicinal ingredients: Trifarotene 0.005% w/w (50 mcg/g). Non-medicinal ingredients: Allantoin, copolymer of acrylamide and sodium acryloyldimethyltaurate with isohexadecane, polysorbate 80 and sorbitan oleate, cyclomethicone 5, ethanol (96%), phenoxyethanol, propylene glycol, purified water, and triglycerides medium-chain.

### **AKLIEF comes in the following dosage forms:**

AKLIEF is available in a 2 g tube (sample) and a 75 g pump.

## WARNINGS AND PRECAUTIONS

### **Do not use AKLIEF if:**

- You have skin conditions, such as eczema or seborrheic dermatitis.
- You are pregnant or planning a pregnancy. If you are a female of childbearing years, you should only use AKLIEF after consulting your doctor about effective birth-control measures.
- You are allergic to the medicinal ingredients in AKLIEF or any of its ingredients (see “**What are the ingredients in AKLIEF?**”).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AKLIEF. Talk about any health conditions or problems you may have, including if:**

- You are breastfeeding or plan to breastfeed. The product should not be applied to the chest, in order to avoid contact with the child.
- You intend to go out in the sun. Exposure to too much sunlight, including sunlamps, should be avoided while using AKLIEF. If you must be out in the sun, use a good sunscreen product (SPF 15 or higher) and protective clothing over the treated areas.
- You have other skin problems, including cuts, abrasions, eczema, or sunburn. You should avoid applying the product to cuts, abrasions, eczema, and sunburned skin. In case of sunburn, allow the skin to heal before using AKLIEF.

- You are using any other acne medications. AKLIEF should not be used with other acne medications unless your doctor tells you to use them.

### **Other warnings you should know about:**

#### **Skin care:**

- Avoid electrolysis, “waxing,” or chemical hair removers on skin treated with AKLIEF. This may increase your skin sensitivity.
- Avoid skin products that may dry or irritate your skin, such as harsh soaps, cleansers, astringents, cosmetics that have strong skin drying effects, and products containing high levels of alcohol, spices, or limes.
- Use non-comedogenic cosmetics. Colour cosmetics, such as blushes and powders, are acceptable; however, make-up cosmetics should be water based only. Cosmetics must be removed by thoroughly cleaning the area before applying AKLIEF.

You should avoid weather extremes, such as wind or cold, as they may be irritating.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.**

## INTERACTIONS WITH THIS MEDICATION

### **The following may interact with AKLIEF:**

- Using AKLIEF with topical medicines that contain sulfur, resorcinol, or salicylic acid may cause skin irritation. Talk to your doctor about stopping your use of other acne products OR about changing the time of day that you use them.

## PROPER USE OF THIS MEDICATION

### **How to take AKLIEF:**

- Use AKLIEF exactly as your doctor tells you to use it.
- AKLIEF is for skin use only. Do not use AKLIEF in or on your mouth, eyes, lips, angles of nose, vagina, axillary region (or armpit), and neck. If product enters the eye, wash immediately with warm water.
- You may use moisturizer before and after applying AKLIEF as needed. Make sure to allow skin to dry before you apply AKLIEF.

### **Usual dose (adults and patients 12 years and older):**

Apply a small amount of AKLIEF to provide a thin layer to the affected areas of the trunk and/or face once a day, in the evening, on clean and dry skin.

Wash your hands before and after application of the cream.

AKLIEF comes in a pump.

- Depress the pump once to dispense a small amount of cream and spread a thin layer over the face (i.e. forehead, cheeks, nose, and chin).
- Two pumps should be sufficient to apply a thin layer to cover the upper trunk (i.e. reachable upper back, shoulders, and chest). One additional pump may be used to apply a thin layer to the middle and lower back, if acne is present.

Apply a thin layer to cover the entire affected area. Do not use more than you need to cover the treatment area. Using too much AKLIEF or using it more than one time a day may increase your chance of skin irritation.

### **Overdose:**

If you think you have taken too much AKLIEF, contact your healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### **Missed dose:**

If a single dose is missed, dosing should continue as per usual the following evening, and the usual amount should be applied. Do not apply extra.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

### **What are possible side effects from using AKLIEF?**

*These are not all the possible side effects you may feel after receiving AKLIEF. If you experience any side effects not listed here, contact your healthcare professional.*

Side effects include:

- Skin redness, dryness, itching, peeling, burning, stinging, and pigment loss of the skin.

The above side effects may happen when your skin is adjusting to AKLIEF's action of unplugging clogged pores. If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional. Your doctor may recommend increasing the use of a moisturizer before or after application, a change in your dose, or a change to how often you use the medication.

### **Reporting Side Effects:**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail, or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## HOW TO STORE IT

### **Storage:**

Store AKLIEF at room temperature (15°C to 30°C). Keep from freezing. Keep out of reach and sight of children.

### **If you want more information about AKLIEF:**

- Talk to your healthcare professional
- This document plus the full Product Monograph, prepared for health professionals, can be found at [www.galderma.ca](http://www.galderma.ca) or by contacting the sponsor, Galderma Canada Inc.

Questions or concerns: 1-800-467-2081

This leaflet was prepared by Galderma Canada Inc.  
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