
The 4th generation retinoïd is coming soon
A new era in acne treatment
AKLIEF®
(trifarotene)
Cream, 50 microgram/g
GALDERMA

NAME OF THE MEDICINAL PRODUCT: Aklief 50 microgram/g, cream. QUALITATIVE AND **QUANTITATIVE COMPOSITION:** One gram of cream contains 50 micrograms of Trifarotene. Excipient(s) with known effect: One gram of cream contains 300 milligrams of propylene glycol (E1520). For the full list of excipients, see section 6.1 of the SKP.
PHARMACEUTICAL FORM: Cream. White and homogenous cream.
THERAPEUTIC INDICATIONS: 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.
POSOLOGY AND METHOD OF ADMINISTRATION: Posology: Apply a thin layer of Aklief cream to the affected areas of the face and/or trunk once a day, in the evening, on clean and dry skin. The duration of treatment should be determined by the doctor based on the clinical response and condition. Special populations: Elderly patients: The safety and efficacy of Aklief in geriatric patients aged 65 years and above have not been established. Renal and hepatic impairment: Aklief has not been studied in patients with renal and hepatic impairment. Paediatric population: The safety and efficacy of Aklief in children below 12 years old have not been established. Method of administration: For cutaneous use only. 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 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. Patients should be instructed to avoid contact with the eyes, eyelids, lips and mucous membranes and to wash their hands after applying the medicinal product. The use of a moisturizer is recommended as needed from the initiation of treatment, while allowing sufficient time before and after the application of Aklief cream to allow the skin to dry. The duration of treatment should be determined by the doctor based on the clinical response and condition.
CONTRAINDICATIONS: Pregnancy (see section 4.6 of the SKP); Women planning a pregnancy; Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SKP.
SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Erythema, scaling, dryness, and stinging/burning may be experienced with use of Aklief cream (see section 4.8 of the SKP). To mitigate the risk of such reactions, patients should be instructed to use a moisturizer from the initiation of treatment, and, if appropriate, reduce the frequency of application of Aklief cream, or suspend use temporarily. Despite mitigation measures, if severe reactions persist the treatment may be discontinued. The product should not be applied to cuts, abrasions, eczematous or sunburned skin. As with other retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with Aklief. If a reaction suggesting sensitivity to any component of the formula occurs, the use of Aklief should be discontinued. Caution should be exercised if cosmetics or acne medications with desquamative, irritant or drying effects are concomitantly used with the medicinal product, as they may produce additive irritant effects. Aklief should not come into contact with the eyes, eyelids, lips, or mucous membranes. If the product enter the eye, wash immediately and abundantly with warm water. Excessive exposure to sunlight, including sunlamps or phototherapy should be avoided during the treatment. Use of a broad-spectrum, water-resistant sunscreen with a Sun Protection Factor (SPF) of 30 or higher and protective clothing over treated areas is recommended when exposure cannot be avoided. This product contains propylene glycol (E1520) that may cause skin irritation.
UNDESIRABLE EFFECTS: Summary of safety profile: Local cutaneous reactions such as erythema, scaling, dryness, and stinging/burning) were collected separately from other adverse events as a measure of local tolerance. These cutaneous reactions are very common and of mild, moderate and severe intensity for up to 39%, 29.7% and 6.2% of patients, respectively on the face. On the trunk, up to 32.9%, 18.9%, 5.2% of patients had mild, moderate and severe reactions respectively. The maximum severity typically occurred at Week 1 for the face, and at Week 2 to 4 for the trunk, and decreased with continued use of the medication (see section 4.4 of the SKP). The most "commonly" reported adverse reactions as described below are application site irritation, application site pruritus and sunburn, occurring in 1.2% to 6.5% of patients treated with Aklief cream in clinical studies. Summary of adverse reactions: Adverse reactions reported in the 12-week vehicle-controlled Phase 3 studies in 1220 patients treated with Aklief cream (and for which the rate for Aklief cream exceeds the rate for vehicle cream) are classified by System Organ Class and frequency, using the following convention: very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to 1<100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data). General disorders and administration site conditions: common: application site irritation, application site pruritus; uncommon: application site pain, application site dryness, application site discolouration, application site erosion, application site rash, application site swelling; rare: application site erythema, application site urticaria, application site vesicles. Injury, poisoning and procedural complications: common: sunburn. Skin and subcutaneous tissue disorders: uncommon: skin irritation, acne, dermatitis allergic, erythema; rare: eczema asteatotic, seborrheic dermatitis, skin burning sensation, skin fissures, skin hyperpigmentation. Eye disorders: rare: eyelid exfoliation, eyelid oedema. Gastrointestinal disorders: rare: cheilitis. Vascular disorders: rare: flushing. In the one-year open label safety study including 453 patients with acne of the face and trunk aged 9 years and older who received Aklief cream, the pattern of adverse reactions was similar to that experienced in the 12-week vehicle-controlled studies.
MARKETING AUTHORISATION HOLDER: Galderma Benelux B.V., Gravinnen van Nassauboulevard 91, 4811 BN Breda, The Netherlands.
MARKETING AUTHORISATION NUMBER(S): BE554142 (pump); BE55413 (tube)/RVG124058.
DELIVERY METHOD: on medical prescription.
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Galderma Benelux B.V.
De Keyserlei 58/60 Bus 19 • 2018 Antwerp • Belgium • Tel. +32 (0)3 897 19 00 • info.be@galderma.com • www.galdermabenelux.com