

Public Summary SwissPAR dated 5 July 2021

Aklief® (active substance: trifaroten)

First authorisation in Switzerland: 16 December 2020

Medicinal product (cream) for external treatment of patients from the age of 12 with moderately severe acne of the face and/or torso

About the medicine

Aklief is a medicine for the treatment of acne containing the active substance trifaroten.

Aklief is used for the external treatment of moderately severe acne in patients from the age of 12 if more than half of the face and/or torso is affected and numerous comedones

(whiteheads and blackheads), pimples and pustules (inflamed pimples) are present.

Acne is a common disorder of the skin. It affects an estimated 50–95% of adolescents in western industrialised countries. Approximately 20–35% of patients have a moderately severe to severe form of acne.

Mode of action

The active substance trifaroten belongs to a group of active substances known as retinoids. Trifaroten binds and activates the so-called retinoic acid receptor¹ (RAR γ). Trifaroten also modifies differentiation and inflammatory processes in the keratinocytes²

and in the reconstructed outer layer of the skin. This mechanism of action enables Aklief to relieve inflammation, stimulate the formation of new skin cells and dissolve blackheads.

1 Receptor: a protein or protein complex capable of binding to a certain signalling molecule which can trigger signalling processes.

2 Keratinocytes: cells in the outer layer of the skin which produce keratin. Keratin protects the skin and gives it stability.

Use

Aklief is available only on prescription. It is authorised for sale in a pump dispenser containing 30 g or 75 g. One gram of cream contains 50 micrograms of the active substance trifaroten.

Aklief should be applied thinly once a day in the evening to clean and dry skin in the affected regions. The duration of treatment

should be decided by the doctor on the basis of the patient's state of health. It is recommended to have the improvement in the condition of the skin assessed by a doctor after 3 months of treatment.

Efficacy

The efficacy of Aklief Cream was investigated in 2 trials over a 12-week period. A total of 2,420 patients aged at least 9 years with moderately severe acne of the face and torso (the latter site was optional for children between 9 and 11 years of age) were enrolled in the trials.

The severity of the acne was defined as moderately severe on a 5-point scale if more than

half of the face and/or torso was affected and numerous blackheads and inflamed pimples were present (the 5-point scale is explained in the Information for healthcare professionals).

In both trials, once-daily application of Aklief improved facial acne and acne affecting the torso after 12 weeks of treatment.

Precautions, undesirable effects & risks

Aklief must not be used in those who are hypersensitive to the active substance or any of the excipients.

Malformation of the unborn child cannot be ruled out when Aklief is used. For this reason Aklief must not be used by women who are pregnant or are planning to become pregnant. Women of childbearing age should use suitable contraception during treatment with Aklief.

The most common undesirable effects observed during use of Aklief are skin irritation, dryness, flaking, itching and sunburn affecting the treated parts of skin. To reduce

the risk of this type of reaction, it is recommended to use a moisturising cream from the start of treatment.

Aklief should only be applied to intact skin and should not come into contact with the eyes, lips or mucous membranes. If the cream gets into the eyes, it must be rinsed out immediately with plenty of warm water.

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

Assessment of submitted scientific data showed that Akliief had a modest but consistent treatment effect in patients with moderately severe acne of the face and/or torso. If all the precautionary measures are observed, the benefits of Akliief outweigh the

risks. Swissmedic has therefore authorised the medicinal product Akliief with the active substance trifaroten for the treatment of patients from the age of 12 with moderately severe acne of the face and/or torso.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Akliief](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

Information for patients (package leaflet): [Information for patients Akliief](#)

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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