LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Aklief
(trifarotene)

SE/H/1863/01/DC

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trifarotene

Cream, 50 mikrogram/g

This is a summary of the public assessment report (PAR) for Aklief. It explains how Aklief was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Aklief.

For practical information about using Aklief, patients should read the package leaflet or contact their doctor or pharmacist.

What is Aklief and what is it used for?

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.

How does Aklief work?

Aklief contains the active substance trifarotene that belongs to a group of medicines called retinoids. The retinoids have comedolytic activity, which means that they reduce the number and formation of comedones (whiteheads and blackheads). Trifarotene has also shown anti-inflammatory and depigmenting activities.

How is Aklief used?

The pharmaceutical form of Aklief is cream for cutaneous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Aklief have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Aklief is effective in 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.

What are the possible side effects of Aklief?

For the full list of all side effects reported with Aklief, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Aklief approved?

It was noted that the effect of Aklief in the 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 was significantly better than treatment with vehicle (a cream with the same ingredients as Aklief except for the active substance trifarotene). Therefore, the Medical Products Agency in Sweden decided that Aklief's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Aklief?

A risk management plan has been developed to ensure that Aklief is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Aklief, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Aklief

The full PAR for Aklief can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Aklief, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-03.