Part VI: Summary of the risk management plan

Summary of risk management plan for Aklief 50 microgram/g cream (trifarotene).

This is a summary of the risk management plan (RMP) for Aklief. The RMP details important risks of Aklief, how these risks can be minimised, and how more information will be obtained about Aklief's risks and uncertainties (missing information).

Aklief's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Aklief should be used.

I. The medicine and what it is used for

Aklief is authorised 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 (see SmPC for the full indication). It contains trifarotene as the active substance and it is given by cutaneous route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Aklief, together with measures to minimise such risks and the proposed studies for learning more about Aklief's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Aklief is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Aklief are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Aklief. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	Teratogenicity: safety during pregnancy
Missing information	Use longer than 1 year Use with concomitant acne medications

II.B Summary of important risks

Important potential risk: Teratogenicity: safety during pregnancy	
Evidence for linking the risk to the medicine	Class effect Like other retinoids, trifarotene could induce teratogenicity. This is consistent with its retinoid-like pharmacological activities.
Risk factors and risk groups	Pregnant women
Risk minimisation measures	Routine risk communication: See SmPC section 4.6., 5.3 and PL section 2. Pregnancy The following recommendations are provided: Aklief is contraindicated during pregnancy or in women planning a pregnancy. If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.
Additional pharmacovigilance activities	None

Important Missing information: Long term exposure > 1 year	
Risk minimisation measures	Routine risk communication: See SmPC section 4.2. The duration of treatment should be determined by the doctor on the basis of the clinical condition.
Additional pharmacovigilance activities	None.

Important Missing information: Use with concomitant acne medications	
Risk minimisation measures	Routine risk communication: See SmPC section 4.5 There is no data on the *pharmacodynamic* interaction potential of trifarotene. 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 (see section 4.4).
Additional pharmacovigilance activities	None.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Aklief.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Aklief.