LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tolak
(fluorouracil)

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Summary Public Assessment Report

Tolak

(fluorouracil)

Cream 40 mg/g.

This is a summary of the public assessment report (PAR) for Tolak. It explains how Tolak 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 Tolak.

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

What is Tolak and what is it used for?

Tolak is a cream used to treat skin conditions called actinic keratosis (sun damaged skin) Grade I and II on the face, ears, and/or scalp in adults.

How does Tolak work?

The active substance fluorouracil (FU) belongs to a group of medicines known as antimetabolites which inhibit the growth of cells (cytostatic agent).
Due to its structural similarity with the thymine (5-methyluracil) occurring in nucleic acids, FU prevents its formation and utilisation and in this way inhibits both DNA and RNA synthesis which results in growth inhibition. By inhibiting the growth of the cells in the actinic keratosis lesions the lesions can be cleared.

How is Tolak used?

The pharmaceutical form of Tolak is cream for topical 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.

What benefits of Tolak have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Tolak is effective in treating non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade I and II) of the face, ears, and/or scalp in adults.

What are the possible side effects of Tolak?

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

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

Why is Tolak approved?

It was noted that the effect of Tolak in the treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade I and II) of the face, ears, and/or scalp in adults was significantly better than treatment with placebo in in two primary, multi-centers, randomized, controlled studies. Therefore, the Medical Products Agency in Sweden decided that Tolak'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 Tolak?

A risk management plan has been developed to ensure that Tolak 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 Tolak, 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 Tolak

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

This summary was last updated in 2020-01.