EMA/356530/2021
EMEA/H/C/005183

# Klisyri (*tirbanibulin*)

An overview of Klisyri and why it is authorised in the EU

## What is Klisyri and what is it used for?

Klisyri is an ointment used to treat adults with mild actinic keratosis on the face and scalp. Actinic keratosis is a precancerous, abnormal skin growth that develops after too much exposure to sunlight.

Klisyri contains the active substance tirbanibulin. It is available as 250-mg sachets, each containing 2.5 mg of tirbanibulin.

## How is Klisyri used?

A thin layer of Klisyri is applied to the affected areas on the face or scalp once a day for five consecutive days. Klisyri should not be applied to open wounds or broken skin.

The patient's response to the treatment should be evaluated about 8 weeks after the start of treatment. If the actinic keratosis has not cleared completely at the time of evaluation, other treatment options should be considered.

The medicine can only be obtained with a prescription. For more information about using Klisyri, see the package leaflet or contact your doctor or pharmacist.

## How does Klisyri work?

The active substance in Klisyri, tirbanibulin, works by stopping cells in the skin growth from dividing and making new cells. It does so by attaching to a protein called tubulin, which is an important component of the cells' structural 'skeleton' (microtubules). This attachment stops the microtubules from growing, preventing especially the fast-growing cells from dividing and causing them to die.

Tirbanibulin also blocks certain enzymes called tyrosine kinases, which can be involved in cell division.

## What benefits of Klisyri have been shown in studies?

Two main studies, each involving 351 patients with actinic keratosis in the face and scalp, showed that Klisyri was effective in clearing actinic keratosis from the affected areas of the skin. Patients applied either Klisyri or placebo (a dummy treatment) on the affected areas for 5 days and were evaluated about 8 weeks (57 days) after starting treatment.

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In the first study, actinic keratosis cleared completely in 44% of patients using Klisyri compared with 5% of those using placebo. Similarly, in the second study, actinic keratosis cleared completely in 54% of patients using Klisyri compared with 13% of the patients using placebo.

## What are the risks associated with Klisyri?

The most common side effects with Klisyri (which may affect more than 1 in 10 people) are local skin reactions, including erythema (reddening of the skin), flaking/scaling, crusting, swelling and the formation of sores and ulcers.

Other side effects with Klisyri (which may affect up to 1 in 10 people) are blisters, pruritus (itching) and pain at the application site.

For the full list of side effects and restrictions of Klisyri, see the package leaflet.

## Why is Klisyri authorised in the EU?

Two studies showed that that Klisyri was effective at clearing actinic keratosis from the affected skin of patients. The side effects were considered mild to moderate and were reversible. The European Medicines Agency therefore decided that Klisyri's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Klisyri must investigate the risk of actinic keratosis progressing to skin cancer following treatment in a 3-year safety study.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Klisyri have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Klisyri are continuously monitored. Suspected side effects reported with Klisyri are carefully evaluated and any necessary action taken to protect patients.

## Other information about Klisyri

Klisyri received a marketing authorisation valid throughout the EU on 16 July 2021.

Further information on Klisyri can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/klisyri.

This overview was last updated in 07-2021.