

# Information about your actinic keratosis (AK) treatment

This booklet has been produced by Ammirall for patients who have been prescribed Klisyri ▼ (tirbanibulin).  
It is not intended to replace the advice given by your doctor or the package leaflet.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See page 5 for how to report side effects.

# 1

## What is actinic keratosis ?



**Actinic keratoses (also called solar keratoses) are lesions that develop from a specific type of skin cell called keratinocytes.** The cause of actinic keratoses is chronic exposure to the ultraviolet (UV) rays of the sun. UV rays damage the genetic material in these cells and they grow abnormally.



**They are commonly found in people with fair skin, and are more common in middle-aged and elderly individuals.** The lesions are mainly seen on skin areas that are hit directly by sunlight, such as the face, back of the hands, forearms and lower legs. They can also occur on the upper back and chest.



Actinic keratoses normally do not cause symptoms, but may scale, bleed or sting when picked or exposed to sunlight.



**Actinic keratoses are small, crusty, scaly or crumbly patches of skin.**

They may look red or light brown, or be the colour of your skin. The lesions might be dry or rough to touch and sometimes are easier to feel than see. The size of each lesion may vary from a few millimetres up to 1 centimetre or more in diameter.



# 2

## What is Klisyri?

Klisyri is an ointment that has been prescribed to you for the topical treatment of actinic keratosis on the face or scalp. Klisyri is a treatment for mild actinic keratosis in adults and it should only be used for flat actinic keratosis on the face and scalp.

Klisyri contains the active substance tirbanibulin. It comes in single-dose sachets for individual use. **One box contains 5 sachets.**

**This medicine has been prescribed for you only. Do not pass it on to others even if their symptoms are similar.**



It should not be used if your **skin is not healed from any previous medicine, procedure, or surgical treatment.**

# 3

## How should you apply your medication?



**1** First **wash your hands and the treatment area** with soap and water, and then carefully dry yourself.



**2** Open a **new sachet** each time you apply this medicine. Open the sachet along the perforations.



**3** Squeeze some ointment onto your fingertip.



**4** Apply a thin layer of ointment evenly, covering an area of up to 25cm<sup>2</sup> on the face or scalp.



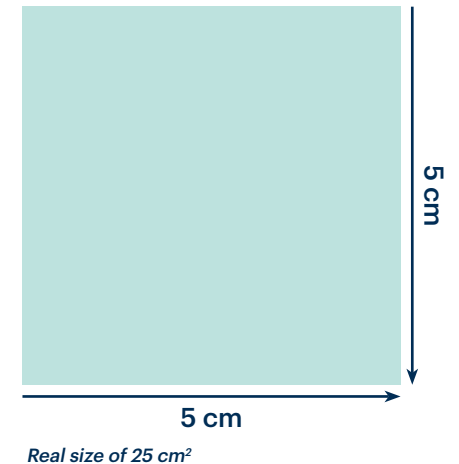
**5** **Wash your hands** with soap and water immediately after application and discard the sachet after use.

Do not apply more ointment than your doctor has advised and do not apply more than once a day.

Each sachet is for single use only and should be discarded after application, even if you have not used the whole amount of ointment. You should not apply more ointment than your doctor has advised.



It should be applied to the affected face or scalp area **once a day** for one treatment cycle (**5 consecutive days**).



Avoid washing and touching the treated area for **approximately 8 hours after application**, and **do not cover the treated area with bandages or block it in any other way**. Following this time, you may wash the area with mild soap and water.

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See section 3 of the package leaflet for further information.

## 4 How long does it usually take to see results?

It takes **5 days to complete the treatment**, and you may see a reduction of AK lesions in a period of 8 weeks. If the treated area does not show complete clearance at about 8 weeks after the treatment cycle started, or new lesions develop within the treatment area, the treatment should be considered by a doctor.



## 5 Are there any potential side effects?

Your medication, like any other treatment, may cause side effects. Potential side effects are local skin reactions (LSRs), application site itching (pruritus), and application site pain.

**LSRs:** Reddening, flaking/scaling, crusting, swelling, blistering and ulceration.

In clinical trials nearly all patients had some LSR's, however, **most were mild to moderate** and resolved without treatment. LSRs typically peak 8 days after starting treatment and generally resolve within 2-3 weeks. Contact your doctor if these side effects get severe.

Please note that overdosing your medication may increase frequency and severity of LSRs.

If you use more Klisyri than you should, wash the treated area with mild soap and water. **Please contact your doctor or pharmacist if you get severe skin reactions.**

See section 3 and 4 of the package leaflet for further information.

## 6 Is there anything else I should be aware of?



**Avoid application around the eyes.** If accidental exposure occurs, flush your eyes with water and seek medical attention. Klisyri should **not be used on the inside of the nostrils, on the inside of the ears, or on the lips.**



**Avoid accidental transfer** of your medication to other areas, or to another person.



After using Klisyri, avoid activities that might cause excessive sweating, and **avoid exposure to sunlight as much as possible** (including sunlamps and tanning beds). When outdoors, wear protective clothing and a hat, as well as sunscreen (do not apply sunscreen to treated area for 8 hours following each application for the 5 days) to prevent the onset of new lesions.



**Do not refrigerate or freeze.**



Before using your medication, tell your healthcare provider about **all of your medical conditions, or problems with your immune system, and if you are pregnant or breastfeeding.** You should not use your medication during pregnancy.



Do not swallow this medicine. Drink plenty of water if you accidentally swallow this medicine, seek medical assistance and take the package leaflet with you.

See section 2 of the package leaflet for further information.

**For further information on actinic keratosis, please see the additional resources below:**



<https://www.nhs.uk/conditions/actinic-keratoses/>

## **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet. You can also report side effects directly (see below):

### **Ireland**

Reporting forms and information can be found at HPRA Website: [www.hpra.ie](http://www.hpra.ie).

Adverse events should be also reported to Almirall Ltd.

Tel. +353 (0) 1431 9836

### **United Kingdom**

Reporting forms and information can be found at MHRA <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should be also reported to Almirall Ltd.

Tel. 0800 0087 399

By reporting side effects, you can help provide more information on the safety of this medicine.