

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using KLISYRI®?

KLISYRI® contains the active ingredient tirbanibulin. KLISYRI® is used to treat actinic keratosis on the face and scalp in adults.

For more information, see Section [1. Why am I using KLISYRI®?](#) in the full CMI.

2. What should I know before I use KLISYRI® ?

Do not use if you have ever had an allergic reaction to KLISYRI® or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use KLISYRI®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KLISYRI® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use KLISYRI® ?

- Apply a thin layer of KLISYRI® to the affected area on the face or scalp once daily for 5 days in a row.
- One sachet contains enough ointment to cover the treatment area. Do not save the opened sachet for use on another day, even if there is still ointment left.

More instructions can be found in Section [4. How do I use KLISYRI®?](#) in the full CMI.

5. What should I know while using KLISYRI®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or pharmacist you visit that you are using KLISYRI®.• Watch for any new scaly red patches, open sores, and raised or warty growths around the treatment area. If you see any, talk to your doctor immediately.• After applying 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 a hat.
Things you should not do	<ul style="list-style-type: none">• Do not get KLISYRI® in your eyes. If it accidentally gets in your eye, rinse the eye thoroughly with plenty of water, seek medical assistance as soon as possible and take this leaflet with you.• Do not apply the ointment internally, to the inside of the nostrils, the inside of the ear or on the lips. If the ointment accidentally touches any of these areas, wash it off by rinsing with water.• Do not swallow this medicine. Drink plenty of water if you accidentally swallow this medicine, seek medical assistance and take this leaflet with you.• Avoid washing or touching the treated area for approximately 8 hours after KLISYRI® has been applied.
Driving or using machines	<ul style="list-style-type: none">• This medicine is not expected to have any effect on your ability to drive or to use machines.
Looking after your medicine	<ul style="list-style-type: none">• Follow the instructions in the carton on how to take care of your medicine properly.• Store below 25°C. Do not refrigerate or freeze.

For more information, see Section [5. What should I know while using KLISYRI®?](#) in the full CMI.

6. Are there any side effects?

Very common side effects include redness, skin scaling, scabs, swelling and loss of the top layer of skin. Common side effects include pain, itching and blisters.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

KLISYRI®

Active ingredient(s): *tirbanibulin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using KLISYRI®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KLISYRI®.**

Where to find information in this leaflet:

- [1. Why am I using KLISYRI®?](#)
- [2. What should I know before I use KLISYRI®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use KLISYRI®?](#)
- [5. What should I know while using KLISYRI®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using KLISYRI® ?

KLISYRI® contains the active ingredient tirbanibulin.

It is used for the treatment of actinic keratosis on the face and scalp in adults. Actinic keratosis is a rough area of skin that has developed in people who have been exposed to too much sunshine over a long time. KLISYRI® should only be used for actinic keratosis on the face and scalp.

2. What should I know before I use KLISYRI®?

Warnings

Do not use KLISYRI® if:

- you are allergic to tirbanibulin, or any of the other ingredients of this medicine (listed in section 7).

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. KLISYRI® should not be used during pregnancy. It is not known if KLISYRI® can harm your

unborn baby. You should use an adequate method of contraception during treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if KLISYRI® passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with KLISYRI®.

Children and adolescents

KLISYRI® is approved for use in adults and is not intended for children and adolescents under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or using any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

If you have previously used KLISYRI® or similar medicines, tell your doctor before starting the treatment.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KLISYRI®.

4. How do I use KLISYRI®?

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

This medicine is intended to treat an area of up to 25 cm² for one treatment course of five days.

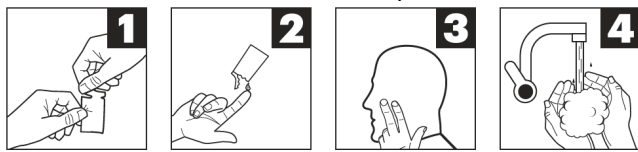
Apply a thin layer of KLISYRI® to the affected area on the face or scalp once daily for 5 days in a row. One sachet contains enough ointment to cover the treatment area as indicated by your doctor. Each sachet is for single use only. Discard sachet after use. Do not save the opened sachet for use on another day, even if there is still ointment left.

When to use KLISYRI®

KLISYRI® should be applied once daily, at approximately the same time each day for 5 days in a row.

How to use KLISYRI®

- Wash your hands with soap and water before applying the ointment.
- Wash the affected area with mild soap and water and dry it gently.
- Open a new sachet each time you apply this medicine.
- Open the sachet along the perforations (Figure 1).
- Squeeze some ointment onto your fingertip (Figure 2).
- Apply a thin layer of ointment evenly over the area indicated by your doctor for treatment (Figure 3).
- Wash your hands with soap and water immediately after applying the ointment (Figure 4).
- Do not wash or touch the treated area for about 8 hours. After this time, you may wash the treated area with mild soap and water.
- Do not cover the treated area with dressings or bandages after you have applied KLISYRI®.
- Repeat the above steps for each day of treatment at around the same time of the day.



If you forget to use KLISYRI®

If you miss a dose, apply the ointment as soon as you remember and then continue with your regular schedule. Do not apply the ointment more than once a day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much KLISYRI®

Wash the treated area with mild soap and water. Please contact your doctor or pharmacist if you get severe skin reactions.

If you think that you have used too much KLISYRI®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning

5. What should I know while using KLISYRI®?

Things you should do

- Wash your hands if you happen to touch the area where you applied the ointment.
- Tell your doctor if you have problems with your immune system.
- After applying 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 a hat.
- Contact your doctor if you get skin reactions to this medicine in the treated area that become severe (see section 6).
- If lesions return or new lesions develop within the treatment area, you should consult your doctor as other treatment options may be considered.
- If you become pregnant while you are taking KLISYRI®, tell your doctor immediately.

Remind any doctor or pharmacist you visit that you are using KLISYRI®.

Things you should not do

- Do not use KLISYRI® until the area to be treated has healed from any previous medicine, procedure or surgical treatment. Do not apply KLISYRI® on open wounds or broken skin.
- Do not get KLISYRI® in your eyes. If it accidentally gets in your eye, rinse the eye thoroughly with plenty of water, seek medical assistance as soon as possible and take this leaflet with you.
- Do not apply the ointment internally, to the inside of your nostrils, the inside of your ear or on the lips. If the ointment accidentally touches any of these areas, wash it off by rinsing with water.
- Do not swallow this medicine. Drink plenty of water if you accidentally swallow this medicine, seek medical assistance and take this leaflet with you.
- Do not cover the treated area with dressings or bandages after using KLISYRI®.
- Do not apply more ointment than your doctor has advised.
- Do not apply the ointment more than once a day.
- Do not allow other people or pets to touch the treated area for around 8 hours after applying the ointment. If the treated area is touched, the area of contact on the other person or pet should be washed.

Driving or using machines

This medicine is not expected to have any effect on your ability to drive or to use machines.

Looking after your medicine

Store KLISYRI® below 25°C. Do not refrigerate or freeze.

For single use only. Discard sachet after use. Do not re-use the sachets once opened.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date which is stated on the outer carton and the label after EXP. The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

After using this medicine, you may get side effects on the skin where you apply the ointment. These side effects may get worse for up to 8 days after you start the treatment, and they typically go away within 2 to 3 weeks after completing the treatment. Contact your doctor if these side effects get severe.

Less serious side effects

Less serious side effects	What to do
<p>Very common side effects (may affect more than 1 in 10 people):</p> <ul style="list-style-type: none">• Redness (erythema)• Skin scaling (flaking)• Scabs (crusting)• Swelling• Loss of the top layer of skin (erosion, ulcer) <p>Common side effects (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none">• Pain (tender, stinging or burning feeling)• Itching (pruritus)• Blisters (vesicles, pustules)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Very rare side effects</p> <ul style="list-style-type: none">• hypersensitivity reactions, signs of hypersensitivity reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.	<p>Call your doctor straight away or go straight to the Emergency Department at</p>

your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects that you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KLISYRI® contains

Active ingredient (main ingredient)	Tirbanibulin Each sachet contains 2.5 mg of tirbanibulin in 250 mg ointment. Each gram of ointment contains 10 mg of tirbanibulin.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Propylene glycol• Glyceryl monostearate 40-55 per cent

Do not take this medicine if you are allergic to any of these ingredients.

What KLISYRI® looks like

Each KLISYRI® sachet contains 250 mg of white to off-white ointment.

Each box contains 5 polyethylene/aluminium foil sachets.
AUST R 391198

Who distributes KLISYRI®

Actor Pharmaceuticals Pty Ltd
North Sydney, NSW 2060, Australia
Telephone: 1800 322 690

This leaflet was prepared in February 2026.