

ACTIKERALL®

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using ACTIKERALL?

ACTIKERALL contains the active ingredients fluorouracil and salicylic acid. ACTIKERALL is used to treat mild to moderate solar keratosis lesions, also known as actinic keratosis lesions or sunspots.

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

2. What should I know before I use ACTIKERALL?

Do not use if you have ever had an allergic reaction to fluorouracil, salicylic acid 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 ACTIKERALL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACTIKERALL 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 ACTIKERALL?

Follow all directions given to you by your doctor or pharmacist. ACTIKERALL should be applied once daily unless your doctor has provided you with other instructions.

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

5. What should I know while using ACTIKERALL?

Things you should do	<ul style="list-style-type: none">Limit your exposure to the sun during treatment with ACTIKERALL.Call your doctor straight away if you become pregnant while using this medicine.Remind any doctor, dentist or pharmacist you visit that you are using ACTIKERALL.
Things you should not do	<ul style="list-style-type: none">Do not use ACTIKERALL to treat any other conditions unless your doctor tells you to.Do not give your medicine to anyone else, even if they have the same condition as you.Do not stop using your medicine without checking with your doctor.Do not let ACTIKERALL come into contact with the eyes, the inside of the mouth or nose or the mucous membranes.
Driving or using machines	ACTIKERALL has no influence on the ability to drive and use machines.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	Store below 25°C. Do not refrigerate. Do not freeze. Keep the bottle tightly closed.

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

6. Are there any side effects?

Common side effects include redness, inflammation, irritation, itching, burning, pain, crusting, whitish discolouration/scaling of the skin, rash, scarring and bleeding in the treatment area. Serious side effects include swelling/soreness of the mouth/tongue and fever/chills. 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 in **Australia**. 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.

WARNING: ACTIKERALL should only be used on a total area no greater than 25 cm² at a time. Use ACTIKERALL only on the face, forehead or bald scalp. Do not use ACTIKERALL on eyelids, lips or mucous membranes.

ACTIKERALL

Active ingredients: *fluorouracil and salicylic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ACTIKERALL. **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 ACTIKERALL.**

Where to find information in this leaflet:

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

1. Why am I using ACTIKERALL?

ACTIKERALL contains the active ingredients fluorouracil and salicylic acid. Fluorouracil belongs to a group of medicines known as antimetabolites which inhibit the growth of cells (cytostatic agent). Salicylic acid is a hard skin softening substance.

ACTIKERALL is used to treat mild to moderate solar keratosis lesions, also known as actinic keratosis lesions or sunspots.

Solar keratoses are rough, red, scaly or crusty spots on the skin that are caused by too much exposure to sunlight. They are more common on sun-exposed areas, such as the face, nose, ears, chest, forearms and back of the hands.

Solar keratoses are usually harmless, but there is a risk that they may turn into skin cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use ACTIKERALL?

Warnings

Do not use ACTIKERALL if:

- you are allergic to fluorouracil, salicylic acid, acetylsalicylic acid (aspirin) or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- you have dihydropyrimidine dehydrogenase (DPD) enzyme deficiency or are taking medicines that could lower your DPD levels. This enzyme plays an important role in the breakdown of fluorouracil. As a result, fluorouracil might accumulate in your body. It may be necessary to have your DPD levels checked before starting treatment with ACTIKERALL.
- you have kidney problems.
- you are pregnant or there is a possibility you may be pregnant.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any inflammatory skin conditions, bleeding skin lesions or any other skin condition. ACTIKERALL contains the ingredient dimethyl sulfoxide which may be an irritant to the skin.
- are using any other dermatological products to treat solar keratoses.
- have or have had DPD (dihydropyrimidine dehydrogenase) enzyme deficiency.
- suffer from a reduced ability to sense touch, pain and temperature. If you have diabetes you may experience these symptoms. In this case, your treatment areas will be closely monitored by your doctor.
- you work outside for long periods of time during the day. Protect your skin from the sun to limit further UV exposure, especially in the area being actively treated with ACTIKERALL. See Section [5. What should I know while using ACTIKERALL?](#)

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.

Do not use this medicine if you are pregnant or if there is a possibility you may be pregnant. It may affect your developing baby if you use it during pregnancy.

Before you start using ACTIKERALL, talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not breastfeed if you are using this medicine. It is unknown whether the active ingredient fluorouracil passes into breastmilk.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

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

Some medicines and ACTIKERALL may interfere with each other. These include:

- medicines used for immunosuppression, or used to treat cancer or viruses such as chicken pox or shingles
- phenytoin, a medicine used to treat epilepsy
- methotrexate, a medicine used to treat cancer and autoimmune diseases
- medicines used to treat diabetes e.g. sulphonylureas.

These medicines may be affected by ACTIKERALL or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

4. How do I use ACTIKERALL?

How much to use

Follow the instructions provided and use ACTIKERALL until your doctor tells you to stop. Only use on face, forehead or bald scalp (excluding eyelids, lips and inside the nose/mouth).

For the first application to the skin:

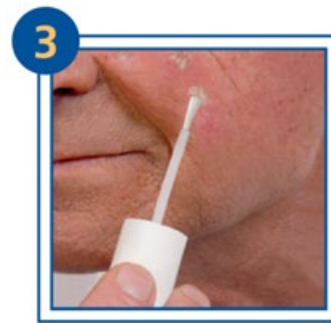
1. To open the bottle, press the lid down and turn.



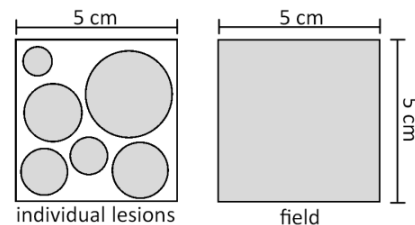
2. Remove excess solution from the brush by wiping it on the neck of the bottle.



3. Dab the solution on the solar keratosis and a small area of healthy skin surrounding it once daily. This rim of healthy skin should be no more than 0.5 cm wide. Do not apply on a total area greater than 25 square centimetres (cm²) at any one time.



Multiple solar keratoses (up to 10 lesions) can be treated simultaneously. The total area of skin being treated with ACTIKERALL at any one time should not exceed 25 cm². As a guide, the rectangle outline drawn on the side of the medicine carton represents a total area of 25 cm². Examples of acceptable treatment areas are below:



Let the solution dry to form a film.
Do not cover with a dressing.

4. Close the bottle properly.



Subsequent applications:

1. Remove the white film on your skin from the previous day's application by simply peeling it off. Warm water may help to remove the film.
2. Follow the instructions as described for the first application.

When to use ACTIKERALL

ACTIKERALL should be applied once daily unless your doctor has told you otherwise.

If you have a solar keratosis in an area of thin skin e.g. around the eyes and temple, your doctor may tell you to apply ACTIKERALL less frequently. If severe side effects occur, your doctor may reduce the frequency of drug application to three times per week until the side effects improve.

It may also be necessary for your doctor to monitor your treatment more often.

How long to use it for

ACTIKERALL is applied to the treatment area once daily until the lesions have completely cleared or for up to a maximum of 12 weeks.

Improvement of solar keratosis can be seen as early as 4 weeks after starting treatment and the improvement increases over time up to 12 weeks.

The clearance of solar keratoses may continue for up to 8 weeks after you have stopped using ACTIKERALL.

If you feel that the product is not working as described, talk to your doctor or pharmacist.

Further instructions

ACTIKERALL must not be allowed to come into contact with the eyes, the inside of the mouth or nose or the mucous membranes.

ACTIKERALL should not be applied to hairy skin as the hair becomes stuck together.

Hair removal such as shaving should be considered prior to applying ACTIKERALL.

ACTIKERALL may permanently stain clothing, fabric or acrylics (such as acrylic bathtubs), so avoid contact with them.

ACTIKERALL is flammable: keep away from fire or flames.

Close the bottle tightly to prevent it from drying out. If ACTIKERALL dries out, it must not be used any longer.

Do not use ACTIKERALL if you notice any crystals.

Do not use ACTIKERALL 3 months after first opening the bottle.

If you forget to use ACTIKERALL

Do not apply more than once daily.

You will be more likely to experience skin reactions and they will be more severe if you use more than recommended.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some suggestions.

If you use too much ACTIKERALL or swallow the solution

If you think that you have used too much ACTIKERALL, or in the case of accidental swallowing, 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 ACTIKERALL?

Your appearance may look worse and you may feel uncomfortable symptoms on the treated area while treatment is in progress. Sometimes it can take several weeks after treatment with ACTIKERALL has stopped before you see any improvement in your condition.

Things you should do:

Limit your exposure to the sun during treatment with ACTIKERALL.

This will help reduce any side effects of the medication.

If you are about to start any new medicine, remind your doctor and pharmacist that you are using ACTIKERALL.

Call your doctor straight away if you:

- become pregnant while using this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using ACTIKERALL.

Things you should not do:

- Do not use ACTIKERALL to treat any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using your medicine without checking with your doctor.
- Do not let ACTIKERALL come into contact with the eyes, the inside of the mouth or nose or mucous membranes.

While treatment is in progress, it is important to consider the following:

- Wherever possible, the skin area treated with ACTIKERALL should be protected against direct sunlight and other forms of ultraviolet radiation using hats and clothing. The treated skin should not be covered with dressings or bandages.
- Before going outdoors, apply a broad-spectrum sunscreen (SPF 30 or higher) over the dried film of ACTIKERALL on the lesion if the skin surface is unbroken (not eroded, scabby, bleeding or exfoliated). Reapply the sunscreen several times during the day.
- ACTIKERALL should not be used on bleeding lesions.
- ACTIKERALL should not be used around the eyes, nose or mouth unless directed by your doctor.
- Avoid cosmetics and other dermatological preparations on the treatment area, unless otherwise instructed by your doctor. Once you stop using ACTIKERALL, talk to your doctor or pharmacist before applying cosmetics or other dermatological products on the affected skin.

Driving or using machines

ACTIKERALL has no influence on the ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C.
- Do not refrigerate.
- Do not freeze.
- Keep the bottle tightly closed.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Once opened, the solution can only be used for 3 months.

Discard 3 months after first opening the bottle.

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 use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• redness• inflammation• irritation• itching• burning• pain• crusting• whitish discolouration and scaling of the skin• rash• scarring• bleeding in the treatment area	Speak to your doctor if you have any of these less serious side effects and they worry you.

These reactions are common and are signs that the medicine is working.

The salicylic acid in ACTIKERALL may cause slight irritation, such as skin inflammation (dermatitis) and contact allergic reactions. Symptoms of contact allergic reactions may include itching, reddening and small blisters even outside the area of application.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• swelling and soreness of the mouth and tongue• fever and chills	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

You may need urgent medical attention or hospitalisation. These side effects are rare.

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

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

Reporting side effects

After you have received medical advice for any side effects 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 ACTIKERALL contains

Active ingredient (main ingredient)	One gram of solution contains: <ul style="list-style-type: none">• 5 mg of fluorouracil, and• 100 mg of salicylic acid
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• dimethyl sulfoxide• ethanol absolute• ethyl acetate• pyroxylin• butyl methacrylate/ methyl methacrylate copolymer (3:1)
Potential allergens	This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

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

What ACTIKERALL looks like

ACTIKERALL is a clear, colourless to slightly orange-white solution. It is packed in a 25 mL brown glass bottle with a child-resistant closure (Aust R 287446).

Who distributes ACTIKERALL?

Australia

Mayne Pharma International Pty Ltd
1538 Main North Road
Salisbury South, SA 5106

Under licence from Almirall

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This leaflet was prepared in October 2025.

For the most up to date version of the Consumer Medicines Information go to actikerall.com.au