

Information about your actinic keratosis treatment

- Information about actinic keratosis
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This leaflet has been produced by Almirall for patients who have been prescribed Actikerall. It is not intended to replace the advice given by your doctor or the package leaflet.

What is actinic keratosis?

Actinic keratosis (also known as a solar keratosis) is the most common skin condition caused by sun damage. Actinic keratoses are small lesions that result from skin being damaged by the sun over many years. UV rays from the sun damage the genetic material in a specific type of skin cell called keratinocytes, causing them to grow abnormally.

- These lesions are most commonly found on areas such as the face, back of the hands and arms, ears, scalp and lower legs.
- They are commonly found in people with fair skin, and are more common in middle-aged and elderly individuals as the risk for actinic keratoses increases with the amount of exposure to the sun.
- Actinic keratoses normally do not cause symptoms, but may scale, bleed or sting when picked or exposed to sunlight.



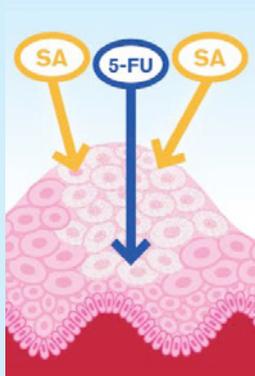
What do actinic keratoses look like?

Actinic keratoses are small, crusty, scaly or crumbly patches of skin and are sometimes easier to feel than see.

- They can be the same colour as your skin or range from pink, to red, to brown
- They are usually between 1-2 cm in size
- They may feel itchy

What is Actikerall?

Actikerall is a solution to treat actinic keratosis in adult patients with a healthy immune system; specifically lesions of mild-to-moderate thickness.



It contains two active ingredients: fluorouracil and salicylic acid.

- Fluorouracil belongs to a group of medicines known as antimetabolites which **inhibit the growth of cells.**
- Salicylic acid acts on **hard skin to soften it.**

Actikerall is a clear, colourless to slightly orange-white solution.



How to use Actikerall

Always use Actikerall exactly as your doctor has instructed. Please check with your doctor or pharmacist if you are not sure. Please read the package leaflet.

Dosage

- Actikerall should not come into contact with the eyes or mucous membranes.
- Apply to lesions once daily unless your doctor has told you otherwise.
- **Multiple actinic keratoses can be treated simultaneously. Up to 10 lesions can be treated at the same time.** The total area of skin being treated with Actikerall at any one time should not exceed 25 cm² (5 cm x 5 cm).

Duration of Treatment

- Actikerall is applied to actinic keratoses once daily until the lesions have completely cleared or for up to a maximum of 12 weeks.
- Improvement of actinic keratoses can be seen as early as 4 weeks after starting treatment and the improvement increases over time up to 12 weeks.
- The clearance of actinic keratoses may continue for up to 8 weeks after stopping treatment.
- Treatment should be continued even in the absence of any effect after the first 4 weeks.

Do not use Actikerall:

- If you are hypersensitive (allergic) to fluorouracil, salicylic acid or any of the other ingredients of Actikerall which are listed on the patient information leaflet in the box
- While breast-feeding
- During pregnancy, or if there is a possibility that you might be pregnant
- In children and adolescents
- If you have kidney problems
- If you are taking certain antiviral medications containing brivudine or sorivudine
- If it could come into contact with the eyes, the inside of the mouth or nose, or the genitals (mucous membranes)

Side Effects

Like all medicines, Actikerall can cause side effects. Because Actikerall is only applied to the surface of the skin, side effects will mostly be experienced at the application site. Mild-to-moderate irritation and inflammation at the site of the application may occur. If these reactions are too strong, stop treatment and contact your doctor. As this medicine has a very strong softening effect on the skin, whitish discolourations and scaling of the skin may occur.

How to apply

If there is still a white film on your skin from a previous application, please peel off carefully or wash off with warm water before each new application.



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



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



- Dab the solution onto the actinic keratosis lesions. Surrounding skin can be treated simultaneously when required, providing the total area does not exceed 25 cm² (5 cm x 5 cm).



- Close the bottle properly. Let the solution dry and form a film. Do not cover with a dressing.