

Package leaflet: Information for the user

Aknemycin Plus

4.0% w/w and 0.025% w/w cutaneous solution

Erythromycin and Tretinoin



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aknemycin Plus is and what it is used for
2. What you need to know before you use Aknemycin Plus
3. How to use Aknemycin Plus
4. Possible side effects
5. How to store Aknemycin Plus
6. Contents of the pack and other information

1. What Aknemycin Plus is and what it is used for

Aknemycin Plus is a treatment for acne which is applied to the skin.

Aknemycin Plus is a solution and contains Erythromycin and Tretinoin as active ingredients. Erythromycin is an antibiotic which kills the germs found in acne and reduces the inflammation of your skin.

Tretinoin encourages the layer of dead and hardened skin cells that form on the skin surface to peel off. At the same time, it clears the blackheads which block your skin pores and cause spots to form. Once the pore is unblocked, sebum can escape so that germ activity is limited. Aknemycin Plus also helps dissolve away the excess oil in your skin.

2. What you need to know before you use Aknemycin Plus

Do not use Aknemycin Plus

- if you are allergic to Erythromycin, Tretinoin or any of the other ingredients of this medicine (listed in section 6).
- if you are suffering from acute eczema, rosacea (a skin disease which affects the face and is characterised by redness, pimples and peeling) or acute inflammatory conditions of the skin, especially around the mouth.
- if your skin is sunburnt.
- if you are using any other medication on your skin which may lead to skin irritation e.g. an exfoliator.
- if you or a member of your family have ever suffered from skin tumours called Cutaneous Epithelioma.
- if you are pregnant
- if you are planning a pregnancy.

If the above apply to you, talk to your doctor before using this medication.

Warnings and precautions

- when applying Aknemycin Plus to the face **do not** let the solution touch your eyes. If by mistake it does, rinse your eyes thoroughly with cold water.
- take care that the solution does not build up in creases in the skin.
- if you have to have an X-ray, remove all traces of Aknemycin Plus from the area to be X-rayed.
- if the solution gets on to your fingers you should wash them thoroughly.
- during treatment with Aknemycin Plus your skin may become more sensitive to UV light therefore, **do not** sunbathe, use sunbeds or sunlamps.
- **do not** apply the solution before swimming.
- Do not light a cigarette or expose yourself to flame until the medicine has dried completely.

Talk to your doctor or pharmacist before using Aknemycin Plus.

Aknemycin Plus solution contains ethanol

This medicine contains 752 mg of alcohol (ethanol) in each ml. It may cause burning sensation on damaged skin.

Other medicines and Aknemycin Plus

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Do not use Aknemycin Plus if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

Do not use Aknemycin Plus when you are breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There are no effects on the ability to drive and use machines when this medication is used.

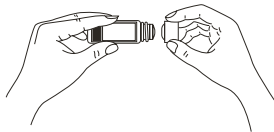
3. How to use Aknemycin Plus

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

- The container has an applicator which allows a simple, hygienic and economic application.
- Before each use press the top of the screw cap on to the foam pad until you “feel” a click, then invert the bottle so that the solution wets the applicator pad, then wipe the applicator over the affected skin areas.



Normally you should apply Aknemycin Plus once or twice daily as advised by your doctor. After use the applicator will close again automatically.



Activating the applicator



Applying the solution

Duration of treatment

Carry on using Aknemycin Plus for as long as your doctor tells you.

- The length of time depends on the condition of your skin but this will normally be between 9 and 12 weeks. It is important that you use Aknemycin Plus regularly.
- There may not be any improvement in your skin condition for several weeks after starting the treatment with Aknemycin Plus.

If you use more Aknemycin Plus than you should

Skin irritation like reddening, drying and discomfort may occur. Reduce the frequency of application if you experience skin irritation or contact your doctor.

If you forget to use Aknemycin Plus

If you forgot to use Aknemycin Plus at the usual time, use it as soon as you remember. **Do not** apply twice the amount to make up for forgetting to use Aknemycin Plus but carry on as before.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For example, when you first use Aknemycin Plus your skin problem may seem to get worse. This is a sign that the medicine is beginning to act. However this should soon pass and you will then see an improvement.

Contact your doctor immediately if you experience a serious skin reaction: a red scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

Rarely, the skin can be irritated by Aknemycin Plus and you may have a sore, dry or burnt feeling or see peeling. In **very rare cases** these symptoms may also be an expression of an allergic reaction. If this happens, see your doctor.

Rarely, the skin may become darker or lighter in colour. People with dark skin may see a lightening of their skin where Aknemycin Plus has been used. This is temporary. Your skin will go back to its usual colour when you stop using Aknemycin Plus.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aknemycin Plus

Keep this medicine out of the sight and reach of children.

Aknemycin Plus should be kept in the outer carton to protect from direct sunlight.

Store below 30°C.

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

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. Contents of the pack and other information

What Aknemycin Plus contains

- The active substances are Erythromycin and Tretinoin.

Each gram of cutaneous solution contains 40 mg of erythromycin and 0.25 mg of tretinoin.

- The other ingredients are ethanol, glycerol and copolyvidone.

What Aknemycin Plus looks like and contents of the pack

Aknemycin Plus is a clear solution.

Aknemycin Plus is available in a 25ml bottle and 50 ml pack (2x25 ml).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Almirall Hermal GmbH

Scholtzstrasse 3, 21465 Reinbek, Germany.

This leaflet was last revised in 04/2020.