SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect:
1 ml of solution contains 752 mg of alcohol (ethanol).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous solution.

Aknemycin Plus is a clear solution for topical administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aknemycin Plus is indicated for the treatment of all forms of acne, both non-inflammatory forms with comedones and inflammatory forms with papules and pustules particularly those associated with a very oily skin.

4.2 Posology and method of administration

Posology

To be applied to the affected areas once or twice daily. Treatment should continue for 9-12 weeks according to the condition of the skin. It should be noted that therapeutic improvement may not be observed for several weeks after starting treatment.
Consistent application makes a significant contribution to the success of the therapy.
Excess application of Aknemycin Plus should be avoided since it may result in marked erythema, drying and discomfort of the treated areas.

The dosage is the same for all ages.

Method of administration

For application to the skin.
The applicator allows direct administration to the skin. The patient should press the top of the screw cap on the foam pad before each use and should feel a 'click' which indicates that the applicator will close again automatically.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- A family history of cutaneous epithelioma.
- In acute eczemas, rosacea and acute inflammatory conditions of the skin, especially around the mouth.
- When underlying sunburn is present
- Concomitant use with other skin medications particularly those containing keratolytic agents (see section 4.5).
- Pregnancy (see section 4.6)
- Women planning a pregnancy.

4.4 Special warnings and precautions for use

Photosensitivity may occur during treatment with Aknemycin Plus. Exposure to sunlight should be minimised and use of sun lamps or sun beds avoided during treatment. Patients with sunburn should not use this product until recovered because of the increased susceptibility to sunlight whilst using tretinoin. Wind and rain may be unusually irritating to patients under treatment.

Accumulation of the product in skin folds or in the angles of the nose should be avoided. The product should not be allowed to come into contact with the eyes or eyelids - if this occurs, thorough rinsing with water is recommended.

As with other macrolides, rare serious allergic reactions, including acute generalised exanthematous pustulosis (AGEP) have been reported. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

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

Do not light a cigarette or expose yourself to flame until the medicine has dried completely.

4.5 Interaction with other medicinal products and other forms of interaction

Skin irritation may be enhanced by UV rays (natural sunlight, sun lamps, sun beds), X-rays or by bathing in chlorinated or salt water.
Any sunburn should be allowed to heal before the start of treatment with Aknemycin Plus.
Aknemycin Plus should not be used concomitantly with other skin medications particularly those containing keratolytic agents (see section 4.3), as this may exacerbate any skin irritation that is present.

4.6 Fertility, pregnancy and lactation

Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally

assumed to result into low systemic exposure due to minimal dermal absorption. However, there could be individual factors (e.g. damaged skin barrier, excessive use) that contribute to an increased systemic exposure.

Pregnancy
Aknemycin Plus is contraindicated (see section 4.3) in pregnancy, or in women planning a pregnancy.
If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.

Breast-feeding
It is known that orally administered retinoids and their metabolites are secreted in breast milk. As a precaution therefore, Aknemycin Plus should be avoided in women who are breast feeding.

4.7 Effects on ability to drive and use machines

Aknemycin Plus has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following frequency categories are used for the evaluation of undesirable effects:

Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1,000 to <1/100)
Rare	(≥1/10,000 to <1/1,000)
Very rare	(<1/10,000)
Not known	(frequency cannot be estimated from the available data)

Skin and subcutaneous tissue disorders:
There may be rare cases of skin irritation in the form of erythema, burning, drying or peeling of the skin may be observed. In very rare cases the above symptoms may also be an expression of a hypersensitivity reaction (allergic contact eczema).There may be an apparent deterioration in acne with an increase in inflammatory symptoms at the commencement of treatment; this is a sign that the medicine is beginning to act and is usually transitory. If the above occurs, treatment should not be interrupted but the frequency of application reduced.

Rarely, a temporary hypopigmentation or hyperpigmentation has been reported in individuals treated with tretinoin. Temporary depigmentation in non-caucasians is possible.

Not known: acute generalised exanthematous pustulosis (AGEP).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Aknemycin Plus is for topical use only. Overdosage will not occur since the amount of erythromycin and tretinoin applied is too small to induce systemic toxicity. If the product is accidentally taken orally, unless the amount is small, gastric lavage should be performed as soon as possible.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Retinoids for topical use in acne. ATC code: D10AD.

Erythromycin is a macrolide antibiotic with bacteriostatic action on all pathogens involved in the development of acne. When applied topically it also effects a reduction in the concentration of skin surface lipids and shows a direct anti-inflammatory effect.

The retinoid tretinoin acts topically as keratolytic agent by markedly increasing cell turnover in the cornified epithelium including the epithelium of the follicular ducts and comedones. In the first instance, skin irritation, erythema and increased vascularization occur followed by thickening and desquamation of the epithelium. The renewal time of the cornified epithelium is therefore shortened.

The alcohol base dissolves sebum.

5.2 Pharmacokinetic properties

Percutaneous absorption or erythromycin is negligible following topical application of Aknemycin Plus solution for several weeks to large areas of skin.

After topical application, up to 6% of the applied dose of tretinoin is recovered in the urine within 50-60 hours, indicating some absorption. The ratio of renal to biliary excretion is approximately 1:3, therefore the maximum likely total absorption is 24%.

5.3 Preclinical safety data

High oral doses of tretinoin are teratogenic in animals and there is evidence of embryotoxicity from studies where tretinoin is applied dermally.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol, glycerol, copolyvidone

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C.
Keep bottle in outer carton to protect from direct sunlight.

6.5 Nature and contents of container

Amber glass bottle, with white screw cap, containing 25ml Aknemycin Plus. The bottle has a polyethylene stopper which holds a foam pad with a nylon gauze covering. Pack sizes 25ml, 50ml (2 x 25ml).

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Aknemycin is an alcohol-based product and is flammable.

7. MARKETING AUTHORISATION HOLDER

Almirall Hermal GmbH
Scholtzstrasse 3
D-21465
Reinbek
Germany

8. MARKETING AUTHORISATION NUMBER(S)

PL 33016/0007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 July 1998

10 DATE OF REVISION OF THE TEXT

02/02/2026