Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986
This medicine is to be supplied by physician's prescription only

AKNEMYCIN

Solution for topical use – for external use
10g solution/0.2g Erythromycin

Composition:
Active ingredient and its concentration –10g of solution for application to the skin contain Erythromycin 0.2g.

Inactive ingredients and allergens in the product: See section "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is this medicine intended for?

For external antibiotic treatment of all forms of acne (skin lesions) particularly inflammatory forms with papules and pustules.

Therapeutic group: Erythromycin – Macrolide antibiotics.

2. Before using this medicine

X Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains
  The inactive ingredients are listed in the section "Additional Information".

! Special warnings regarding the use of this medicine

Before the treatment with Aknemycin, tell your physician:
- If you are sensitive to any food or medicine

Oxidants (oxidizing agents) and water impair the efficacy of the product.
Do not light a cigarette or expose yourself to flames until product has completely dried.

If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist.

Pregnancy and breastfeeding
If you are pregnant or breast-feeding, you should consult a physician or pharmacist before using this medicine.

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure. The dosage and treatment will be determined only by the physician.
The recommended dose is usually direct application to the affected skin areas twice a day.

Do not exceed the recommended dose.
Do not swallow. For external use only.

Manner of use:

Opening instructions – The product's bottle has an applicator at the top, which can be used to apply the product directly on the skin.

Prior to the first use of the product, remove the screw cap, turn it over, and press it downwards against the applicator (see illustration).

This will open the safety lid and enable you to use the product.

The duration of treatment with Aknemycin should not exceed 4-6 weeks.

If there is no improvement in your condition, refer to your physician.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to the physician or to a hospital emergency room and bring the medicine package with you.

Persist with the treatment as recommended by the physician. Consult the physician if you want to stop treatment.

How can you contribute to the success of the treatment?

During the treatment, it is advisable to avoid using substances drying the skin, and to avoid too frequent washing of the affected areas in order to prevent drying of the skin and exacerbation of its condition.

In addition, allow a lapse of at least one hour between applying this medicine and applying other medicines or other products such as: Cosmetics, perfumed toiletries, soaps, shaving creams or lotions etc.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Aknemycin may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Contact the physician immediately if the following side effects, which are very rare, appear:

- Excessive dryness of the skin
- Skin redness
- Local irritation (sensation of tingling and itch)
- Excessive skin peeling
- Rash in the treated area

If a side effect appears, If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage: Store at a temperature below 25˚C.
- Shelf life following first opening of the bottle:
  Once the bottle was opened, this medicine should not be used for longer than 6 months
  Caution! Inflammable, keep away from fire!

6. Additional information

In addition to the active ingredient the medicine also contains:
9.25g ethanol anhydrous, lauryl polyglycol phosphate, glycerol, povidone.

What does the medicine look like and what are the contents of the package:
Aknemycin is a clear colorless solution.
The carton pack contains a bottle containing 25 ml of Aknemycin solution.

Registration holder and his address: Neopharm Ltd, P.O. Box 7063, PetachTiqva 49170
Fax number: 03-9373774 email address: drugsafety@neopharmgroup.com

Manufacturer and his address: Almirall Hermal GmbH, Germany

This leaflet was checked and approved by the Ministry of Health in: 03/2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
064.70.22653