

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine requires a doctor's prescription

Read this package insert carefully
in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health
and its content was checked and approved in June 2007

AFLUMYCIN Cream

Composition:

Prednisolone 0.5%
Gentamicin sulphate 0.16%

Inactive ingredients: Sorbitan mono stearate, polysorbate 60, nyst, spermaceti, cetostearyl alcohol, 2-octyldodecanol, benzyl alcohol, purified water.

Therapeutic activity: The medicine contains two active ingredients: gentamicin - a broad spectrum antibiotic; and prednisolone - a corticosteroid with an anti-inflammatory effect. The combination of the two ingredients gives the preparation efficacy in treating local skin inflammations associated with bacterial infections.

When should the medicine not be used?

Do not use this medicine if you are sensitive to any of its ingredients. Do not use in cases of viral (e.g. herpes or chicken pox) or fungal infections or skin tuberculosis.

Do not use this medicine without consulting a doctor before starting treatment in the following cases:

If you are pregnant or breastfeeding. If you are suffering, or have suffered in the past, from impaired function of the immune system, diabetes (during prolonged use), impaired hearing.

Warnings: If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. Do not use this medicine for any purpose other than that for which it was prescribed. Do not use this medicine on wide areas of skin or on open or infected wounds. Do not allow this medicine to come into contact with the eyes. In case of contact, wash immediately and thoroughly with water. Special caution should be taken when using in children and adolescents. Use at these ages must be carried out under medical supervision.

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, including non-prescription medicines and nutritional supplements, inform the attending doctor in order to prevent hazards or lack of efficacy arising from drug interactions.

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of using this medicine, for example: burning sensation, stinging, irritation, dryness of the skin, hypertrichosis, skin inflammations that resemble acne, skin hypopigmentation.

These side effects usually disappear within a short time following the period of adaptation to the medicine. However, if they continue and/or are bothersome, consult your doctor.

Side effects that require special attention:

In cases of hypersensitivity to the drug accompanied by local irritations, the development of a local infection, inflammation or rash at the application site or in case these conditions worsen (rare): stop treatment and refer to your doctor.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

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

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

Dosage: Dosage is according to doctor's instructions only. Recommended dosage unless otherwise prescribed by your doctor: Gently apply a thin layer of cream on the affected area 4 times a day. During treatment, the dosage should be gradually decreased, in accordance with the doctor's recommendation. Do not exceed the recommended dosage. If there is no improvement in your condition within a week, consult your doctor again. Do not extend treatment for more than 3 weeks in infants or children under 4 years of age, especially on areas covered by diapers. Unless otherwise directed by the doctor, avoid occlusive dressings on the affected area (plastic diapers for a baby are considered occlusive dressings).

Attention: Do not swallow! This medicine is intended for external use only. Avoid contact with the eyes and mucous membranes (mouth and nose). See paragraph "Warnings".

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor!

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbours or acquaintances. Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: In a cool place, below 25°C. After first opening can be used for 6 months. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

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Manufacturer: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.