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

The medicine is dispensed with a doctor's prescription only

Aflumycin

Cream

Active ingredients and their quantities per dosage unit:
Each tube contains:
Prednisolone 0.5%
Gentamicin sulfate 0.16%
Inactive and allergenic ingredients in the medicine – see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information" in the leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is indicated for the treatment of skin inflammation associated with bacterial infection.

Therapeutic group:
The medicine contains two active ingredients:
Gentamicin – a broad-spectrum aminoglycoside antibiotic.
Prednisolone – corticosteroid with an anti-inflammatory effect.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to the active ingredients or to any of the additional ingredients in this medicine.
- Do not use in case of viral infections (e.g., herpes or chickenpox) or tuberculosis.
- If you have a sensitivity to another topical corticosteroid.
- Do not use to treat a skin reaction to vaccine administration.
- Do not use to treat acne.
- Do not use to treat skin ulcers.
- Do not use to treat rosacea.
- Do not use to treat atrophic skin disease.
- Do not use to treat perioral dermatitis.

Special warnings regarding use of the medicine

- **Before treatment with Aflumycin, tell the doctor if:**
  - you are pregnant or planning to become pregnant
  - you are breastfeeding or planning to breastfeed
  - you are in need of facial skin treatment
- Use Aflumycin on the skin only. Do not allow the medicine to come into contact with the eyes, region around the eyes and mouth.
- Do not use this medicine on deep and open wounds or on mucosal tissues.
- Some of the inactive ingredients in Aflumycin may reduce the efficacy of agents and contraceptives made of rubber, such as condoms and diaphragms.
- Use of topical antibiotics may cause excessive growth of organisms not susceptible to antibiotics, including fungi. If this occurs, or if you have irritation, sensitivity or a super-infection, stop using Aflumycin and start appropriate treatment.

Children and adolescents
Treatment with Aflumycin must be for the shortest possible amount of time and on the affected area only.
This guideline is particularly important when treating wide areas on the body, areas under dressings and in children.

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
If you start taking a new medicine or if you are already being treated with another corticosteroid, tell the doctor or pharmacist.

Pregnancy, breastfeeding and fertility
Pregnancy and breastfeeding
If you are pregnant or breastfeeding, or think you may be pregnant, do not use the medicine without consulting a doctor before treatment.

Fertility
There is no information regarding fertility.

Driving and operating machinery:
There is no information regarding the effect of the medicine on driving and operating machinery.

Important information about some of the ingredients of the medicine
This medicine contains 10 mg/g benzyl alcohol, which may cause mild localized irritation.
The medicine also contains cetostearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis).

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is usually:
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 recommendations.
Treatment of infants and children
Do not extend treatment for more than 3 weeks in infants and 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).
Do not exceed the recommended dose.
If there is no improvement in your condition within one week, refer to a doctor again.
Method of administration
Do not swallow! This medicine is intended **for external use only.**
If you use a large amount of Aflumycin or you use it for a long period of time, you may notice the following symptoms in the treated area:
- the skin will be thinner
- pink/purple stretch marks will appear
- a network of thin and tiny blood vessels will appear

If you experience these symptoms, stop using Aflumycin and refer to the doctor. These symptoms usually pass approximately two weeks after stopping treatment.
Excessive application of topical corticosteroids on wide areas of the body and for prolonged periods of time may increase the risk of side effects. Speak to your doctor about it.
If you have accidentally taken a higher dosage
If you have taken an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do so even if there are no signs of discomfort or toxicity.
If you forgot to take the medicine
If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the dose at the usual time and consult the doctor.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Aflumycin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Stop using Aflumycin if you experience an allergic skin reaction.
An allergic reaction may include the following symptoms:
- shortness of breath
- wheezing or breathing difficulties
- swelling of the face, lips, tongue or other parts of the body
- rash
- itching
- urticaria

Tell the doctor if you experience the following side effects and they worry you:
- itching
- stinging/burning sensation
- redness

The above list includes the more common side effects.
Additional side effects
Rare side effects (effects occurring in 1-10 in 10,000 users)
- skin thinning
- appearance of small blood vessels on the skin surface
- stretch marks
- acne
- hair follicle infection
- hypertrichosis
- redness and irritation around the mouth
- skin discoloration
- allergic skin reactions
- photosensitivity

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
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://sideeffects.health.gov.il
In addition, they can be reported to Padagis via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Store in a cool place, below 25°C.
After the first opening, can be used for 6 months.
Caution! Inflammable - Keep away from fire! Do not light a cigarette or come into contact with fire until the preparation has completely dried.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
  2-octyl dodecanol, cetostearyl alcohol, sorbitan monostearate, cetyl esters wax (walrat), polysorbate 60, benzyl alcohol, purified water.
- What the medicine looks like and the contents of the package: aluminum tube that contains a white cream.

Manufacturer and registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 12591.24928
This leaflet was revised in April 2023 according to MOH guidelines.