Prescribing Information

1. NAME OF THE MEDICINAL PRODUCT

Aflumycin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Prednisolone 0.5%
Gentamicin Sulfate 0.16%

Aflumycin dermal cream contains Prednisolone 5 mg/g (0.5%) and Gentamicin Sulfate 1.6 mg/g (0.16%).

Excipients with known effect:
Aflumycin contains Cetostearyl alcohol and Benzyl alcohol.

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Dermal white cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of skin inflammation associated with bacterial infection.

4.2 Posology and method of administration

Aflumycin is for external topical use only.
Apply a thin layer to the affected skin area 4 times daily.
A gradual dose reduction should be made, according to the physician instructions.
If clinical improvement is not achieved by one week, the condition should be assessed.

Infants and children under the age of 4 years
The treatment duration should not exceed 3 weeks, especially in areas covered by diapers.

Elderly (over 65 years):
No data available.

Paediatric use
In infants and children, plastic pants and napkins may act as occlusive dressings and increase absorption. Because of children's larger skin surface area to bodyweight ratio, paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than adults. Chronic/long-term corticosteroid therapy may interfere with growth and development of children. Use of topical corticosteroids in children should be limited to the least amount required for therapeutic effect.

Effects on laboratory tests
No data available.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

- Aflumycin is contraindicated in viral diseases (e.g. vaccinia, varicella/herpes zoster) and when tuberculous or syphilitic processes and post-vaccination skin reactions are present in the area to be treated. If rosacea, ulcera, atrophic skin diseases, acne vulgaris or perioral dermatitis are present, Aflumycin must not be applied to the face.

4.4 Special warnings and precautions for use

- Aflumycin should not be allowed to come into contact with deep open wounds, muscosae or the eyes when being applied to the face.

- Additional specific therapy is required in skin conditions infected with bacteria and/or fungi. Any spread of infection requires withdrawal of topical corticosteroid therapy.

- If signs of hypersensitivity develop, Aflumycin should be discontinued and appropriate treatment instituted.

- Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

- As known from systemically administered corticosteroids, glaucoma may also develop from using topical corticosteroids (eg. after large-dose or extensive application over a prolonged period, application under occlusive dressings, or application to skin around or near the eyes).

- Aflumycin containss steroid for topical application. As with all corticosteroids, the possibility of hypothalamic-pituitary-adrenal (HPA) axis suppression resulting from percutaneous absorption of corticosteroids must be considered when initiating or reviewing therapy, as adequate studies are not available to define the degree of risk.

- Treatment of large areas has been noted to produce some suppression of cortisol secretion, but plasma levels remain above the lower limit of the normal range and circadian rhythm is maintained. Nevertheless, when treating large areas the duration of use should be kept as brief as possible. Extensive application of topical corticosteroids to large areas of the body or for prolonged periods of time, in particular under occlusion, significantly increases the risk of side effects. This is particularly important in children who may absorb proportionately larger amounts of topical corticosteroid and thus be more susceptible to systemic toxicity.

- Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated.

- Local atrophy, telangiectasia and striae may occur after prolonged treatment or excessive application. Treatment should be discontinued if symptoms such as cutaneous atrophy occur (see also Section 4.8 Adverse effects (Undesirable effects).

- The use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs, or if irritation, sensitization, or superinfection develops, treatment with Aflumycin should be discontinued and appropriate therapy instituted.

- This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). The cream also contains benzyl alcohol which may cause allergic reactions and mild local irritation.

- Some of the excipients in Aflumycin may reduce the effectiveness of latex products such as condoms and diaphragms

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

No specific information exists on interactions with other medications.

4.6 Pregnancy and lactation

Pregnancy:
Gentamicin Sulfate
Because of the potential risk of inner ear and renal damage to the fetus, gentamicin should not be used in pregnancy unless no other treatment options are available.

Lactation:
Gentamicin is excreted in human breast milk and was detected in low concentrations in serum of breast-fed children.
When considering use during lactation, note that after systemic administration, very small amounts of glucocorticoid may be present in breast milk
The benefit of breastfeeding for the child and the benefit of therapy for the woman should be taken into account

4.7 Effects on ability to drive and use machinery

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

In clinical studies, most frequently observed side-effects included application site burning and application site pruritus.
Frequencies of side-effects observed in clinical studies and given in the table below are defined according to the MedDRA frequency convention: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1,000; <1/100), rare (>1/10,000, <1/1,000); very rare (<1/10,000), not known (cannot be estimated from available data). MedDRA version 12.0 was used for coding.

System Organ Class	common	uncommon	rare	not known
General disorders and administration site reaction	application site burning, application site pruritus	application site dryness, application site erythema, application site vesicles,	application site cellulitis, application site oedema, application site irritation	

		application site folliculitis, application site rash, application site paraesthesia		
Immune system disorders		Drug hypersensitivity		
Skin and subcutaneous tissue disorders			pyoderma, skin fissures, telangiectasia, skin atrophy, fungal skin infection, acne	photosensitiztion

As with other corticoids for topical application, the following local side effects may occur: skin atrophy, skin striae, application folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discolouration, and hypersensitivity to any of the ingredients of the formulation. Systemic effects due to absorption may occur when topical preparations containing corticoids are applied.

Post-marketing
Eye disorders: vision blurred.

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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il
In additionally, you can report to Padagis via the following address: padagis.co.il

4.9 Overdose

Excessive dosing may occur with prolonged or intensive topical use. Refer to Section 4.8 Adverse effects (Undesirable effects) for further information.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Prednisolone
After topical application, Aflumycin has anti-inflammatory, anti-pruritic and vasoconstrictive actions.

As for all other glucocorticoids, the mechanism of action of Prednisolone is not completely understood. It is known that Prednisolone binds to the intracellular glucocorticoid receptor. The steroid-receptor complex binds to certain regions of DNA, inducing anti-inflammatory, anti-pruritic and vasoconstrictive effects.

Binding of Prednisolone to the steroid receptor results in the induction of lipomodulin synthesis. Lipomodulin, a protein secondary messenger (also known as lipocortin 1 and macrocortin) inhibits release of arachidonic acid, which in turn inhibits the formation of inflammatory mediators, such as prostaglandins and leukotrienes.

The immunosuppressive action of glucocorticoids can be explained in part by their inhibitory effects on chemotaxis (inhibition of leukotriene synthesis). Glucocorticoids also have antimitotic activity, which is not well understood.

The vasoconstrictive activity of glucocorticoids results from the inhibition of prostaglandin synthesis. Prostaglandins have vasodilatory actions. Glucocorticoids also potentiate the vasoconstrictive effect of adrenaline.

Gentamicin Sulfate
Gentamicin Sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin.
Bacteria susceptible to the action of gentamicin sulfate include sensitive strains of Streptococci (group A beta-hemolytic, alpha-hemolytic), Staphylococcus aureus (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria, Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Proteus vulgaris an Klebsiella pneumoniae.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-Octyl Dodecanol
Cetostearyl alcohol
Sorbitan mono stearate
Cetyl Esters wax (Walrat)
Polysorbat 60
Benzyl alcohol
Purified water

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

After first opening: 6 months.

6.4 Special precautions for storage

Store in a cool place below 25°C.
Caution! Inflammable - Keep away from fire!

6.5 Nature and contents of container

Aflumycin is available in 20g Aluminium tubes with polyethylene caps.

7 Manufacturer

Padagis Israel Pharmaceuticals, 1 Rakefet St., Shoham, Israel

8 Registration Holder

Padagis Israel Pharmaceuticals LTD, 1 Rakefet St., Shoham, Israel

9 Registration Number

125-91-24928

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