

1. NAME OF THE MEDICINAL PRODUCT

Aureocort Ointment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Aureocort Ointment is a topical preparation containing the active ingredients chlortetracycline hydrochloride 3.09 w/w and triamcinolone acetonide 0.1 w/w.

3. PHARMACEUTICAL FORM

Ointment for topical administration.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Aureocort combines the anti-inflammatory action of triamcinolone acetonide with the anti-infective properties of chlortetracycline.

It is indicated in the treatment of secondarily infected atopic dermatitis, contact dermatitis, eczema, neurodermatitis, otitis externa, seborrhoeic dermatitis, varicose eczema, vesiculopustular dermatitis. It may also be used in the treatment of infected insect bites.

4.2. Posology and Method of Administration

Recommended doses and dosage schedules:

Adults, children over 8 years and the elderly

Aureocort Ointment should be applied sparingly to the affected area, either directly or on sterile gauze, two or three times daily.

Aureocort treatment should be limited to seven days. (see section 4.4)

Avoid contact with eyes (see section 4.4)

In general, dose selection for an elderly patient should be cautious, taking into account physiological changes in ageing skin (see section 4.4)

4.3 Contraindications

The use of Aureocort is contra-indicated in tuberculous, fungal or viral lesions of the skin (herpes simplex, vaccinia and varicella), and primary bacterial infections, e.g. impetigo, pyoderma, furunculosis, in acne vulgaris rosacea, perioral dermatitis and widespread plaque psoriasis (see Section 4.4)

Aureocort Topical preparations are also contra-indicated in patients with a history of hypersensitivity to tetracyclines, corticosteroids, or any other ingredient in the preparations.

4.4 Special warnings and precautions for use

General Use

Corticosteroids, such as triamcinolone, may be absorbed in sufficient amounts to cause systemic corticosteroids effects, if applied to large areas, to broken skin or under occlusive dressings. Systemic absorption of topical corticosteroids has produced reversible hypothalamic- pituitary-adrenal (HPA) axis suppression, manifestation of Cushing's syndrome hyperglycaemia, and glucosuria in some patients.

Minor degrees of adrenal suppression may occur when Aureocort Ointment is applied over relatively small areas under an occlusive dressing. Occlusion should not be used when treating conditions of the face.

Chlortetracycline, like other tetracycline-class antibiotics, may cause foetal harm when administered to a pregnant woman (see section 4.6).

The use of corticosteroids on infected areas should be continuously and carefully observed, bearing in mind the potential spreading of infections (caused by organisms not sensitive to chlortetracycline) by anti-inflammatory corticosteroids. It may be advisable to discontinue corticosteroid therapy and/or initiate alternative antibacterial measures in these circumstances. Generalised dermatological conditions may require systemic corticosteroid therapy.

Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since in this situation occult extension of infection may occur due to the masking effect of the steroid. Extended or recurrent application may increase the risk of contact sensitisation and should be avoided.

Hypersensitivity reactions to the anti-infective component may be masked by the presence of the corticosteroid.

Phototoxic reactions can occur in individuals using chlortetracycline, and are characterized by severe burns of exposed surfaces resulting from direct exposure of patients to sunlight during therapy with chlortetracycline. Patients exposed to direct sunlight or ultraviolet light (artificial sunlight) should be advised that this reaction can occur, and treatment should be discontinued at the first evidence of erythema of the skin.

A moderately potent or potent corticosteroid may be appropriate for severe atopic eczema on the limbs, for 1–2 weeks only, switching to a less potent preparation as the condition improves. In an acute flare-up of atopic eczema, it may be appropriate to use more potent formulations of topical corticosteroids for a short period to regain control of the condition. A very potent corticosteroid should be initiated under the supervision of a specialist. Continuous daily application of a mild corticosteroid such as hydrocortisone 1% is equivalent to a potent corticosteroid such as triamcinolone 0.1% applied intermittently.

Avoid prolonged use on the face (and keep away from eyes).Caution should also be applied when using this preparation on the periorbital area of the face, as it can induce ocular complications that include cataract, glaucoma, retarded healing or corneal abrasion, extension of herpetic infection, and increased susceptibility of bacterial and fungal infection.

Aureocort ointment should be used with caution in patients with psoriasis as it may result in rebound relapses following the development of tolerance, including generalised pustular psoriasis. It may also result in local and systemic toxicity due to impaired barrier function of the skin. Absorption is more likely after repeated applications, possibly by greater skin permeability in psoriatic areas than normal skin. Use in cases where the approved indication/s co-exist with psoriasis.

Paediatric Use

Paediatric patients may demonstrate a greater susceptibility to topical corticosteroid induced hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio and are also therefore more susceptible to systemic toxicity.

HPA axis suppression (and Addisonian crisis upon withdrawal), Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Avoid prolonged use in children and use under specialist supervision.

Chronic corticosteroids therapy may interfere with growth and development of children.

The use of drugs of the tetracycline class during tooth development may result in permanent discolouration of the teeth (see section 4.6).

This adverse reaction is more common during long-term use of the drug, has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Tetracycline drugs, therefore, should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.

To reduce the theoretical risk of damage to permanent dentition to tetracyclines. Aureocort ointment should not be used in children under 8 years of age, unless other drugs are likely to be effective or are contra-indicated.

Geriatric Use

Clinical studies of topical triamcinolone acetonide-chlortetracycline hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, taking into account physiological changes in ageing skin, usually starting at the low end of dosing range.

4.5. Interactions with other Medicinal Products and other forms of Interaction

Not applicable.

4.6. Pregnancy and Lactation

Topical administration of corticosteroids to pregnant rabbits has been reported to cause abnormalities of foetal development, including cleft palate and intrauterine growth retardation at relatively low doses. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied triamcinolone acetonide-chlortetracycline hydrochloride preparations. Chlortetracycline, like other tetracycline-class antibiotics, may cause foetal harm when administered to a pregnant woman. As this agent is absorbed percutaneously, teratogenicity following topical application cannot be excluded. If any tetracycline is used during pregnancy or if the patient becomes pregnant while using this drug, the patient should be informed of the potential hazard to the foetus.

The use of corticosteroid/antibiotic preparations, containing drugs of the tetracycline class, during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discolouration of the teeth (yellow-grey-brown). This adverse reaction, related only to tetracyclines, is more common during long-term use of the drug, but has been observed following repeated short-term courses. Enamel hypoplasia has also been

reported. Tetracycline drugs, therefore, should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.

Triamcinolone acetonide-chlortetracycline hydrochloride topical preparations should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation

It is not known whether topical administration of corticosteroid-chlortetracycline antibiotic preparations result in systemic absorption to produce quantities in human milk, and it is therefore advised that this preparation is not used during lactation.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Undesirable Effects

Information on side effects according to the body system are as follows:

System Organ Class Adverse Reaction

Immune system disorders: Hypersensitivity

Skin and subcutaneous
tissue disorders:

Application site reactions, including contact dermatitis, skin atrophy, steroid purpura, striae, skin fragility, exfoliative dermatitis, burning sensation, acneiform eruption, folliculitis, rosacea, periocular and perioral dermatitis, delayed wound healing, granulomas, telangiectases, erythema, hypopigmentation, hypertrichosis, masking or aggravation of dermatophyte infection and secondary infection or aggravation of existing infection, photosensitivity, rash, urticaria, pruritus

A few patients may be allergic to any of the components. If an adverse reaction occurs, medication should be discontinued.

Use of topical corticosteroids, such as triamcinolone, in the periorbital region may result in ocular complications (see section 4.4).

Under certain circumstances sufficient amounts of topical corticosteroids, such as triamcinolone, can be absorbed to cause systemic corticosteroid effects including adrenal suppression and Cushing's syndrome. Cessation of topical steroid therapy after an extended treatment period can result in Addisonian crisis.

Chlortetracycline, like other tetracycline-class antibiotics, may cause foetal harm when administered to a pregnant woman, and may cause permanent discolouration of the teeth during development in children up to the age of 8 years (see section 4.6).

4.9. Overdose

Under certain circumstances topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects including Cushing's syndrome. Cessation of topical

steroid therapy after an extended treatment period can result in an Addisonian crisis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Aureocort Ointment contains two active ingredients:

- (i) Chlortetracycline hydrochloride is a broad spectrum antibiotic. It is active against a large number of gram-positive and gram-negative bacteria, including some which are resistant to penicillin.
- (ii) Triamcinolone Acetonide is a corticosteroid with anti-inflammatory, anti-pruritus and anti-allergic effects.

5.2. Pharmacokinetic Properties

Topically applied tetracycline preparations are not absorbed into the general circulation to any significant degree.

Absorption of triamcinolone acetonide from topically applied preparations is usually minimal. However, corticosteroids may be absorbed in sufficient amounts to cause systemic effects if applied to large areas, when the skin is broken, or under occlusive dressings.

5.3. Pre-clinical Safety Data

Nothing of any relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Paraffin white soft, wool fat.

6.2. Incompatibilities

None known.

6.3. Shelf-Life

3 years.

6.4. Special Precautions for Storage

Do not store above 25°C. Store in the original pack..

6.5. Nature and Content of Container

Collapsible aluminium tubes with white, high density polyethylene caps.

6.6. Instruction for Use, Handling and Disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 12762/0143

9. DATE OF FIRST AUTHORISATION, RENEWAL OF THE AUTHORISATION

1st May 2005

10. DATE OF REVISION OF THE TEXT

26/05/2011