

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

ARISTOCORT topical cream & ARISTOCORT topical ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: 0.02% w/w triamcinolone acetonide.

Triamcinolone acetonide is a white or almost white crystalline powder. Triamcinolone acetonide 11 mg is approximately equivalent to 10 mg of triamcinolone. It is practically insoluble in water, sparingly soluble in alcohol, very slightly soluble in ether. The molecular formula of triamcinolone acetonide is $C_{24}H_{31}FO_6$ with a molecular weight of 434.5.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

ARISTOCORT cream is a smooth, white opaque homogeneous cream, free of visible contamination.

ARISTOCORT ointment is an off white, smooth, homogeneous opaque ointment, free of visible contamination.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In the treatment of the following dermatoses; atopic dermatitis, eczematous dermatitis, nummular eczema, contact dermatitis, anal and vulval pruritus, otitis externa, seborrhoeic dermatitis, eczematized psoriasis, neurodermatitis.

4.2 Dose and method of administration

Apply in small quantities to the affected areas three or four times daily. Some cases of eczematized psoriasis may be treated more effectively by the application of ARISTOCORT under an occlusive nonpermeable dressing.

4.3 Contraindications

- Tuberculosis of the skin, fungal infections and viral diseases of the skin (Herpes simplex, chicken-pox and baccinia).
- Hypersensitivity to any component of the cream or ointment.

- Not to be used in the eye.
- Topical steroids should not be used in patients with markedly impaired circulation since skin ulceration has occurred in these patients following the use of corticosteroids.
- Topical steroids should be used with caution and occlusive dressings should not be used in patients with primary skin infections.

4.4 Special warnings and precautions for use

FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES.

If irritation develops, ARISTOCORT should be discontinued and alternative therapy instituted.

Prolonged and heavy doses of triamcinolone acetonide may have an immunosuppressant effect and thus decrease resistance to infection as well as mask signs of it. If infection of the skin is present suitable antifungal or antibacterial agents should be used first. Any occlusive dressings should be discontinued. If the infection does not respond promptly to therapy, corticosteroid therapy should be discontinued until the infection has been controlled.

Where very large areas are treated for long periods (e.g. atopic dermatitis), the possibility of systemic absorption exists, particularly if an occlusive dressing is applied. Prolonged use of large quantities of topical corticosteroids may also result in atrophic striae or acne eruptions.

Due to the possible systemic absorption of topical steroids, there may be a need for periodic evaluation of hypothalamo-pituitary-adrenal (HPA)-axis suppression by using the urinary free cortisol test or the corticotrophin stimulation test. If the HPA-axis suppression is evident, withdrawal should be attempted and the frequency of application reduced.

Paediatric use

Long term therapy in infants should be avoided as adrenal suppression may occur.

Manifestations of adrenal suppression in children include retardation of linear growth, delayed weight gain, low plasma cortisol concentrations and lack of response to corticotrophin stimulation (see section 5.2 Pharmacokinetic properties). Manifestations of intracranial hypertension include bulging fontanelles, headache and bilateral papilloedema. Topical corticosteroid therapy in children should be limited to the minimum amount necessary for therapeutic efficacy; chronic topical corticosteroid therapy may interfere with growth and development. Parents should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, since such garments may constitute occlusive dressings.

Children have a greater surface to mass ratio than adults, and so may be at greater risk of adverse events from increased dosages.

Any corticosteroid therapy tends to elevate blood glucose levels in diabetic patients, and this should be monitored during treatment.

Corticosteroids should be used cautiously in patients with non-specific ulcerative colitis, diverticulitis, colon abscess or other pyogenic infection, colon obstruction, or extensive fistulas and sinus tracts, fresh intestinal anastomoses, active or latent peptic ulcers, renal insufficiency, hypertension, osteoporosis and myasthenia gravis.

Topical corticosteroids should be used with caution in the management of psoriasis, as exacerbation of the disease or pustular psoriasis may occur during or on withdrawal of topical corticosteroid therapy.

Topical corticosteroids should also be used with caution in patients with impaired T cell function or in those patients receiving other immunosuppressive therapy. The immunosuppressive effects of corticosteroids may be associated with impairment of the normal function of T cells and macrophages. The result of this impairment may be the activation of latent infection or exacerbation of intercurrent infections, including those caused by Candida, Mycobacterium, Toxoplasma, Strongyloides, Pneumocystis, Cryptococcus, Nocardia and Amoeba.

Patients on long term therapy, if there is a risk of immunosuppression, should not be given any live attenuated vaccines.

The use of steroids on infected areas should be attended with caution and careful observation, bearing in mind the potential spreading of infections by anti-inflammatory steroids and the possible advisability of discontinuing steroid therapy and/or initiating antibacterial measures. If infection of the tissues is present, the use of a systemic broad spectrum antibiotic may be desirable.

Generalised dermatological conditions may require systemic corticosteroid therapy.

It must be remembered that steroid therapy, although responsible for remissions of dermatoses, especially of allergic origin cannot be expected to prevent recurrence.

The use of steroids over extensive body areas, with or without occlusive nonpermeable dressings may result in systemic absorption of the corticosteroid being used and the doctor should be aware of such possible absorption and appropriate precautions should be taken.

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.

Rebound effect

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations.

4.5 Interactions with other medicines and other forms of interaction

The drug interactions that can occur with triamcinolone acetonide are those that are common to corticosteroids. There are many potential drug interactions with corticosteroids however most are quite unlikely with topical therapy, occurring mainly with prolonged or over-use.

Carbamazepine, phenytoin and rifampicin all induce hepatic enzymes and thus lead to increased metabolism of triamcinolone acetonide.

Concomitant use of diuretics, which also deplete potassium ion concentration in the blood, may cause hypokalaemia.

All corticosteroids antagonise the effects of neuromuscular blocking agents, such as vecuronium.

Oral contraceptives have been shown to prolong the half-life of triamcinolone acetonide and thus potentiate its anti-inflammatory effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

Like other corticoids, triamcinolone acetonide has demonstrated potent teratogenic effects in pregnant animals after inhalation, subcutaneous and intramuscular administration during organogenesis. Dose related teratogenic effects in rats and rabbits at $\geq 20 \mu\text{g}/\text{kg}/\text{day}$ included cleft palate and/or internal hydrocephaly and axial skeletal defects, while teratogenic effects observed in monkeys at $\geq 500 \mu\text{g}/\text{kg}/\text{day}$ were predominantly CNS and/or cranial malformations.

In vivo studies using pregnant animals have also shown that application of large amounts of topical corticosteroids over prolonged periods may cause fetal abnormalities. There are no adequate and well controlled studies in pregnant women. Therefore, topical corticosteroids should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. These drugs should not be used on extensive areas, in large amounts or for prolonged periods in pregnant women. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

Lactation

It is not known whether topical corticosteroids are distributed into milk; however, systemic corticosteroids are distributed into milk. Topical corticosteroids should be used with caution in nursing mothers.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Local intolerance to ARISTOCORT is rare, but may be manifested by itching and/or irritation at the site of application. Local intolerance may result from idiosyncratic reaction to components other than the triamcinolone acetonide.

Where occlusive, nonpermeable dressings are used, miliaria, folliculitis and pyodermas will sometimes develop beneath the occlusive material. Localised atrophy and striae have been reported with the use of steroids by the occlusive technique.

Topical corticosteroids may cause adverse dermatological effects. Adverse dermatological effects are most likely to occur in intertriginous and facial areas. Local adverse corticosteroid effects occur most frequently with occlusive dressings, especially with prolonged therapy, and may require discontinuation of the dressings. Atrophy of the epidermis, subcutaneous tissue and dermal collagen; drying and cracking or tightening of the skin may occur. Epidermal thinning, telangiectasia, increased fragility of cutaneous blood vessels, pupura and atrophic striae are also reported.

Other adverse dermatologic effects of topical corticosteroids include acneform eruption, vesiculation, irritation, pruritis, hypertrichosis, rosacea-like eruptions on the face, erythema, hyperthesia, perioral dermatitis, burning or stinging sensation, folliculitis, and hypopigmentation.

Adverse dermatological effects usually improve when the drug is discontinued but may persist for long periods; atrophic striae may be permanent. In addition to the other adverse dermatological effects of topical corticosteroid therapy, maceration of the skin and miliaria may occur, especially when occlusive dressings are used. Topically applied steroids are generally nonsensitising, but allergic contact dermatitis may occur rarely.

Topical corticosteroids should be used with caution in the management of psoriasis (see section 4.4 Special warnings and precautions for use).

Topical corticosteroids should also be used with caution in patients with impaired T cell function or in those patients receiving other immunosuppressive therapy. The result of this impairment may be the activation of latent infection or exacerbation of intercurrent infections (see section 4.4 Special warnings and precautions for use).

Any cardiovascular adverse events are unlikely with topical hydrocortisone therapy however, prolonged prolific use may result in a transient hypertension as a result of fluid retention.

Long term corticosteroid use has resulted in Benign Intracranial Hypertension, with most reports occurring in children.

Corticosteroids have documented effects on serum lipids, including increased total cholesterol, increased low density lipoproteins and increased triglyceride levels.

Topical and systemic corticosteroid therapy has been implicated in posterior subcapsular cataract formation, elevated intraocular pressure, optic nerve damage, papilloedema and central serous chorioretinopathy (CSCR). Cataracts, although primarily reported with systemic corticosteroid use, have been reported with use of topical preparations.

General disorders and administration site conditions: Rebound effect

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

Acute ingestion or accidental poisoning, even in massive doses, is rarely a clinical problem. Treatment should be symptomatic and supportive. Excessive chronic exposure results in adverse systemic effects. In such cases the use of topical corticosteroid should be discontinued, with the consideration to tapering the dose. Emesis or activated charcoal is not usually indicated unless multiple ingestion is suspected. Support the patient as necessary and treat symptomatically.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Triamcinolone is a corticosteroid with mainly glucocorticoid activity. The anti-inflammatory activity of 4 mg triamcinolone is equivalent to about 5 mg of prednisolone. On topical application, corticosteroids produce anti-inflammatory, antipruritic and vasoconstrictor actions. The activity of the drugs is thought to result at least in part from binding with a steroid receptor. Corticosteroids decrease inflammation by stabilising leukocyte lysosomal membranes, preventing release of destructive acid hydrolyses from leukocytes; inhibiting macrophage accumulation in inflamed areas; reducing leukocyte adhesion to capillary endothelium; reducing capillary wall permeability and oedema formation; decreasing complement components; antagonizing histamine activity and release of kinin from substrates; reducing fibroblast proliferation, collagen deposition, and subsequent scar tissue formation; and possibly by other mechanisms as yet unknown.

5.2 Pharmacokinetic properties

The rate and extent of triamcinolone acetonide absorption through the skin varies

among individual patients. Following topical application of a corticosteroid to most areas of normal skin, only minimal amounts of the lipophilic drug partitions into the predominantly dermo-epidermal layer (viable epidermis+dermis) and subsequently the systemic circulation.

Absorption is, however, markedly increased when the skin has lost its keratin layer or the rate limiting properties of the stratum corneum. Physical disruption of the stratum corneum, inflammation and/or disease of the epidermal barrier (e.g. psoriasis, eczema) may result in increased absorption. Topical corticosteroids are absorbed to a greater degree from the skin behind and around the ear region, scrotum, axilla, eyelid, face and scalp than forearm, knees, elbow, palm and sole. Prolonged absorption persists even after the area of application has been washed, possibly because the drug is retained in the stratum corneum and/or the dermo-epidermal layer.

Triamcinolone acetonide is reported to have a half-life in plasma of about 2 to over 5 hours. It is bound to plasma albumin to a much smaller extent than hydrocortisone. Triamcinolone acetonide is metabolised in the liver and most tissues to biologically inactive compounds which are excreted in urine.

Children are at a greater risk of systemic absorption of topical steroids due to higher permeation properties of the skin and increased surface area to body mass ratio.

5.3 Preclinical safety data

Long term animal studies have not been performed to evaluate the carcinogenic potential of topical triamcinolone acetonide.

There was no evidence of drug related carcinogenicity in rats or mice given triamcinolone acetonide for 2 years at oral doses up to 1.0 µg/kg/day, respectively. In another 2 year carcinogenicity study, rats given triamcinolone acetonide (4.8 µg/kg/day) budesonide (50 µg/kg/day) or prednisolone (368 µg/kg/day) in the drinking water demonstrated an increased incidence of hepatic tumours for all three drugs. These tumours are likely to represent a class effect, potentially involving glucocorticoid receptors.

No genotoxicity studies have been conducted with triamcinolone acetonide.

Triamcinolone acetonide had no adverse effect on fertility in male or female rats given oral doses up to 15.0 µg/kg/day. However, developmental toxicity, including increases in fetal resorptions and stillbirths, and decreases in pup body weight and survival occurred at oral doses ≥ 5.0 µg/kg/day, with dystocia and prolonged delivery also observed at doses ≥ 8.0 µg/kg/day

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aristocort cream contains the following excipients: emulsifying wax, isopropyl palmitate, glycerol, sorbitol solution (70 per cent) (non-crystallising), lactic acid, benzyl alcohol (preservative) and purified water.

Aristocort ointment contains the following excipient: white soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

30 g and 100 g aluminium tube.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription medicine.

8. SPONSOR

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

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DATE OF FIRST APPROVAL

31/12/1969

9. DATE OF REVISION OF THE TEXT

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All sections revised	Update to the SPC-style format
4.4 & 4.8	4.4: Addition of 'visual disturbance' safety text at the request of Medsafe. 4.8: Addition of central serous chorioretinopathy (CSCR) as an adverse event.
All	Minor text movement and reformatting e.g. addition of footer, addition of pack size and availability statement, correction of telephone number. Addition of section 4.7 heading and content and section number references for clarity.
1, 4.4 & 4.8	1: Deletion of registered symbol from trade name. 4.4: Addition of 'rebound effect' safety text at the request of Medsafe. 4.8: Addition of 'rebound effect' adverse reaction.