PRESCRIBING INFORMATION

PrARISTOCORT® R
Triamcinolone acetonide cream, USP
Cream 0.1 % w/w, topical

Triamcinolone acetonide ointment, USP
Ointment 0.1 % w/w, topical

PrARISTOCORT® C
Triamcinolone acetonide cream, USP
Cream 0.5 % w/w, topical

Topical Corticosteroid

ACTION

Topical steroid products are effective because of their anti-inflammatory, antipruritic and vasoconstrictive properties.

INDICATION

Indicated for topical therapy of corticosteroid responsive acute and chronic dermatoses, where an anti-inflammatory, anti-allergenic and antipruritic activity in topical management is required.

ARISTOCORT R (triamcinolone acetonide cream 0.1% w/w and triamcinolone acetonide ointment 0.1% w/w) and ARISTOCORT C (triamcinolone acetonide cream 0.5% w/w) topical preparations have been demonstrated to be effective in the adjunctive treatment of the following dermatoses: atopic dermatitis, pruritus vulvae and ani, generalized erythroderma, external otitis, seborrheic dermatitis, eczematized psoriasis, neurodermatitis.

The concentrated 0.5 % w/w ARISTOCORT C preparation has been of greatest usefulness in the initial suppression of the acute manifestations of difficult to manage dermatologic conditions. The regular 0.1% w/w ARISTOCORT R preparations are indicated for the control of dermatoses, once difficult conditions are suppressed.

ARISTOCORT R ointment is preferable to ARISTOCORT R and ARISTOCORT C creams when one is dealing with a dry lesion, whereas the ARISTOCORT R and ARISTOCORT C cream base formulations are preferable on weeping lesions.

It must be remembered that steroid therapy, although responsible for remissions of dermatoses, especially of allergic origin, cannot be expected to prevent recurrence. In the case of contact or allergic dermatitis, it is important to investigate causal factors and to remove the offending material or allergen.

CONTRAINDICATIONS

Topical steroids are contraindicated in:

1. Untreated bacterial, tubercular and fungal infections involving the skin, and in certain viral diseases such as herpes simplex, chicken pox, and vaccinia.
2. Hypersensitivity to any of the components.

WARNINGS

The safety of topical corticosteroids during pregnancy and lactation has not been established. The potential benefit of topical corticosteroids, if used during pregnancy and lactation, should be weighed against possible hazard to the foetus or the nursing infant. If used under an occlusive dressing, particularly over extensive areas, sufficient absorption may take place to give rise to adrenal suppression and other systemic effects.

Topical corticosteroids are not for ophthalmic use.

PRECAUTIONS

Should not be used on lesions close to the eye. Although hypersensitivity reactions have been rare with topically applied steroid products, the drug should be discontinued, and appropriate therapy initiated if there are signs of reaction.

Prolonged use of topical corticosteroid products may produce atrophy of the skin and of subcutaneous tissues, particularly on flexor surfaces and on the face. If this is noted, discontinue the use of this product.

In cases of bacterial infections of the skin, appropriate antibacterial agents should be used as primary therapy. If it is considered necessary, the topical corticosteroid product may be used as an adjunct to control inflammation, erythema and itching.

The product should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation.

If symptomatic response is not noted within a few days to a week, the local applications of corticosteroid should be discontinued, and the patient re-evaluated. During the use of topical corticosteroids secondary infections may occur. Significant systemic absorption may result when steroids are applied over large areas of the body. To minimize this possibility, when long-term therapy is anticipated, interrupt treatment periodically or treat one area of the body at a time. Patients should be advised to inform subsequent physicians if there is an elevation of body temperature.

ADVERSE EFFECTS

When occlusive dressings are used, pustules, miliaria, folliculitis and pyoderma may occur. The following adverse skin reactions have been reported with the use of topical steroids: dryness, itching, burning, local irritation, striae, skin atrophy, hypertrichosis, change in pigmentation and secondary infection. Adrenal suppression has also been reported following topical corticosteroid therapy.

Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

DOSAGE AND ADMINISTRATION

Apply in small quantities to the affected areas 3 or 4 times daily.

SUPPLIED

Cream
ARISTOCORT R (triamcinolone acetonide cream 0.1% w/w), regular strength, available in 30 g tubes and 500 g jars.

Non-Medicinal Ingredients: Benzyl Alcohol, Emulsifying Wax, Glycerin, Isopropyl Palmitate, Lactic Acid, Purified Water and Sorbitol Solution.

ARISTOCORT C (triamcinolone acetonide cream 0.5% w/w), concentrated strength, available in 15 g tubes and 50 g tubes.

Non-Medicinal Ingredients : Benzyl Alcohol, Emulsifying Wax, Glycerin, Isopropyl Palmitate, Lactic Acid, Purified Water and Sorbitol Solution.

Ointment
No preservatives.

ARISTOCORT R (triamcinolone acetonide ointment 0.1% w/w) regular strength, available in 30 g tubes.

Non-Medicinal Ingredients: White Petrolatum.

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