

REGISTERED PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ADVANTAN CREAM, OINTMENT, FATTY OINTMENT

Corticoid skin preparations

COMPOSITION

1 g Advantan contains methylprednisolone aceponate (21-acetoxy-11 β -hydroxy-6 α -methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione) 1 mg.
The cream contains benzyl alcohol 1% (w/w) as preservative.

PHARMACOLOGICAL CLASSIFICATION

A. 13.4.1 Corticosteroids without anti-infective agents.

PHARMACOLOGICAL ACTION

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

INDICATIONS

Endogenous eczema (atopic dermatitis, neurodermatitis), contact eczema, dyshidrotic and other eczemas.

CONTRA-INDICATIONS

Tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. herpes simplex, vaccinia, chickenpox, shingles).

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore Advantan should not be used during pregnancy.

DOSAGE AND DIRECTIONS FOR USE

For external use only.

The Advantan formulation appropriate to the skin condition is applied thinly once per day to the diseased areas of skin.

In general, the duration of use should not exceed 12 weeks in adults and 4 weeks in children.

The respective bases are of major importance to the therapeutic effect of the Advantan formulations.

Advantan cream

As a low-fat formulation with a high water content, Advantan cream is particularly suitable for acute and weeping stages of eczema, for very greasy skin and for use on exposed or hairy parts of the body.

If the skin dries out excessively under protracted use of Advantan cream, a switch should be made to one of the fattier formulations (Advantan ointment or fatty ointment).

Advantan ointment

Skin conditions which are neither weeping nor very dry require a base with balanced proportions of fat and water. Advantan ointment makes the skin slightly greasy without retaining warmth and fluid. Of the three formulations, Advantan ointment has the widest field of use.

Advantan fatty ointment

Very dry skin conditions and chronic stages of skin diseases require an anhydrous base. The occlusive effect of the fatty ointment base promotes the healing procedure.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Local concomitant symptoms such as itching, burning, erythema or vesiculation may occur under treatment with Advantan.

The following side-effects may occur: folliculitis, hypertrichosis, perioral dermatitis, allergic skin reactions to one of the ingredients of the formulations.

Long-term continuous treatment with topical corticosteroids should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses. These changes are particularly likely to occur on the face and when occlusive dressings are used. Acneiform skin conditions can occur under therapy with potent corticoids.

Systemic absorption of topically applied corticosteroids may occur, particularly under the following conditions: when large quantities are used, or when application is made to wide areas of the body, or to damaged skin, when potent topical corticosteroids are used, and when the occlusive dressing technique is applied. Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur. These effects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign increased intracranial pressure has been rarely reported.

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted. If fungal infections are present, a topically active antimycotic should be applied.

Topical corticosteroids should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced. If rosacea or perioral dermatitis is present, Advantan must not be applied to the face.

Advantan should not be allowed to come into contact with the eyes when being applied to the face.

Advantan should be used with caution in nursing mothers.

Regular review should be made of the necessity for continuing therapy.

This corticosteroid preparation should not be used in the nappy areas in infants for flexural eruptions, and

ideally it should not be applied to infants and young children.

The treatment of psoriasis with potent topical corticosteroids may provoke the pustular form of the disease.

Advantan should not be applied to skin crease areas.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Please refer to the paragraph "Side-effects and special precautions". If any symptoms of overdosage occur, treatment must be discontinued.

IDENTIFICATION

Cream : White opaque cream.
Ointment : White to yellowish-white opaque ointment.
Fatty ointment : White to yellowish translucent fatty ointment.

PRESENTATION

Tubes of 15, 20, 30, 50 or 100 g.

STORAGE INSTRUCTIONS

Advantan cream and Advantan ointment: Store below 25°C.
Advantan fatty ointment: Store below 30°C.
Keep out of reach of children.

REGISTRATION NUMBER

Advantan cream : X/13.4.1/384
Advantan ointment : X/13.4.1/385
Advantan fatty ointment : X/13.4.1/386

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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