

CONSUMER MEDICINE INFORMATION

ADVANTAN[®]

1g cream or ointment contains 1 mg methylprednisolone aceponate.

What is in this leaflet

Please read this leaflet carefully before you start using ADVANTAN[®]. It will advise you about how to use ADVANTAN[®] properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

This preparation has been prescribed for you personally and you should not pass it on to others. It may harm them.

What is ADVANTAN used for and how does it work

ADVANTAN[®] is an anti-inflammatory medicine (a corticosteroid) to be used on the skin. ADVANTAN[®] suppresses inflammatory and allergic skin reactions and thus relaxes symptoms originating from the skin problem like redness (erythema), thickening of the skin, coarseness of the skin surface, fluid build-up (oedema), itchiness, and other complaints (burning sensation or pain).

ADVANTAN[®] is used for the treatment of atopic dermatitis (endogenous eczema, neurodermatitis), eczema in children, contact eczema, or degenerative, dyshidrotic, or vulgar eczema.

ADVANTAN[®] is available in two different formulations which have a different therapeutic effect which are listed below.

- ADVANTAN[®] cream

ADVANTAN[®] cream has a high water and low fat content. ADVANTAN[®] cream is particularly suitable for acute and so-called weeping stages of eczema, for very greasy skin and for use on exposed or hairy parts of the body.

- ADVANTAN[®] ointment

In certain skin ailments where the skin is neither very dry nor in a weeping state (that is, producing fluid), treatment requires a foundation with balanced proportions of fat and water. ADVANTAN[®] ointment makes the skin slightly greasy without retaining warmth and fluid. Of the two formulations, ADVANTAN[®] ointment has the widest field of use.

Before you use ADVANTAN[®]

Do not use ADVANTAN[®] if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use ADVANTAN[®].

When you must not use it

Do not use ADVANTAN[®] if you have an allergy to:

- any medicine containing methylprednisolone aceponate.
- any of the ingredients listed at the end of this leaflet.
- any other similar medicine, that is topical corticosteroids.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face lips, tongue or other parts of the body; rash, itching or 'hives' on the skin.

Do not use ADVANTAN[®] if:

- you have infection due to:
 - tuberculosis (TB) or syphilis
 - a virus such as chicken-pox or shingles
 - a skin reaction following a vaccination.

Do not use ADVANTAN[®] if have:

- acne
- rosacea
- ulcera
- atrophic skin disease or
- perioral dermatitis (redness and irritation around the mouth)

If any of these above conditions appear for the first time while using ADVANTAN[®], stop using it at once and consult your doctor.

What else you should know

Prolonged use (longer than 4 weeks) should be avoided (see the side effects section of this leaflet).

If your doctor diagnoses that your skin disease is accompanied by bacterial or fungal infections, additional specific therapy is required. Any spread of infection may require withdrawal of topical corticosteroid therapy.

If your skin dries out excessively under use of ADVANTAN[®] cream, a switch should be made ADVANTAN[®] ointment, the formulation with a higher fat content.

If you apply ADVANTAN[®] to the face, it should not be allowed to come into contact with your eyes.

Do not put ADVANTAN[®] in your mouth or allow the product to come in contact with deep open wounds or mucous membranes.

If you have already suffered a previous case of glaucoma, be sure to inform your doctor. As known from systemic corticosteroids, glaucoma may also develop from using corticosteroids (for example, after large-dosed or extensive application over a prolonged period, air-tight or water-tight dressing techniques, or application to the skin around the eyes).

No impairment of adrenal gland function has been observed either in adults or in children on large-area (40 - 60% of the skin surface) or even air-tight or water-tight dressing treatment when ADVANTAN, has been used for 12 weeks in adults and 4 weeks in children. Nevertheless, the duration of use should be kept as brief as possible on the treatment of large areas.

- **ADVANTAN[®] and other medicines**

Please inform your doctor or pharmacist if you are using or have recently used any other medicines, even those for which you needed no prescription.

- **ADVANTAN[®] and pregnancy**

If you are pregnant, your doctor will want to consider this before prescribing the use of ADVANTAN[®], so please mention that you are or could be pregnant. As a general rule, topical preparations containing corticosteroids should not be applied during the first three months of pregnancy. In particular, large-area or prolonged use of air-tight or water-tight dressing should be avoided. If you suspect that you are pregnant while you are already using ADVANTAN[®], you should consult your doctor as soon as possible.

- **ADVANTAN[®] and breast-feeding**

If you are breast-feeding a baby or small child, you should not apply ADVANTAN[®] to the breasts. Treating large areas, prolonged use or air-tight or water-tight dressings should be avoided.

Your doctor will want to consider the fact that you are breast-feeding before prescribing the use of ADVANTAN[®], so please mention this. In particular, large-area or prolonged use must be avoided.

How to use ADVANTAN[®] properly

Your doctor will decide which ADVANTAN[®] formulation (cream, ointment) is best suited for you. Unless otherwise prescribed by the doctor, you should apply ADVANTAN[®] thinly once per day to the affected areas of skin.

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

If you have the impression that the effect of ADVANTAN[®] is too strong or too weak, talk to your doctor or pharmacist.

Overdosage

No risk is to be expected from a one-time overdose (that is, when applied once to a large skin area) or from accidental swallowing.

Telephone your doctor or the Poisons Information Centre (in New Zealand, National Poison Centre, telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or someone else may have used too much or swallowed some of this medicine. Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by ADVANTAN[®].

Like all medicines, ADVANTAN[®] can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

The most common side effects are:

- itching
- burning

The following list includes side effects that are rare:

- skin infection at the site of application
- swelling at the site of application
- application site irritation
- redness
- bacterial skin infection
- cracks on the skin
- fungal skin infection
- thinning of the skin
- the appearance of fine blood vessels on the skin surface
- stretch marks
- acne
- infection of hair follicles at the application site

- excessive unwanted hair growth
- skin discolouration
- allergic skin reactions to any of the ingredients of the formulations.

If you notice any side effects not mentioned in this leaflet or if the original symptoms of your skin ailment should re-occur, please inform your doctor or pharmacist.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

Do not use after the expiry date stated on the package.

ADVANTAN[®] cream / ointment: Do not store above 25°C.

Store all drugs properly and keep them out of reach of children.

Further information

Pack size: Tubes contain 15g ADVANTAN[®], cream or ointment.

ADVANTAN[®] contains:

active substance

Methylprednisolone aceponate

other substances

Cream

decyl oleate, glycerol monostearate 40-55%, cetostearyl alcohol, hard fat, caprylic-capric-stearic acid triglyceride (Softisan 378) polyoxyl-40-sterate, glycerol 85%, disodium edetate, benzyl alcohol, butyl hydroxytoluene, purified water

Ointment

white soft paraffin, liquid paraffin, white beeswax, Dehymulus E, purified water

If you have any further questions please consult your doctor or pharmacist.

Sponsor

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