

Package leaflet: Information for the patient
Advantan 0.1% ointment
methylprednisolone aceponate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Advantan is and what it is used for
2. What you need to know before you use Advantan
3. How to use Advantan
4. Possible side effects
5. How to store Advantan
6. Contents of the pack and other information

1. What Advantan is and what it is used for

Advantan contains methylprednisolone aceponate, a potent corticosteroid.

Advantan is used for the treatment of eczema (non contagious, inflammatory dermatitis, that affect the skin surface) such as:

- constitutional eczema (atopic dermatitis, neurodermatitis),
- eczema vulgaris,
- allergic and irritative contact dermatitis,
- dyshidrotic eczema,
- eczema in children

The formulation of Advantan ointment assures an appropriate amount of lipids to the skin without blocking transpiration and exchanges of heat. Given its characteristics, Advantan ointment has a broad field of application, from skin conditions that are not excessively secreting to those that are not particularly dry.

2. What you need to know before you use Advantan

Do not use Advantan

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if the area to be treated is affected by tuberculosis or syphilis;
- if the subject has viral infections (e.g. chicken pox or shingles);
- if the subject has skin conditions accompanied by bacterial or fungal infections;
- if the subject has rosacea (redness and desquamation in areas of the face);
- if the subject has an inflammation of the skin around the mouth (perioral dermatitis);
- if the subject has ulcers, acne vulgaris or atrophic dermatitis;
- if there are skin reactions to vaccinations (redness) in the area to be treated.

Warnings and precautions

Corticosteroids must only be administered at the lowest dosages possible, particularly in children, and only for the time strictly necessary to achieve and maintain the desired therapeutic effect.

The use of cutaneous products, especially for prolonged periods, can cause sensitization and cause side effects. If this happens, you should suspend treatment and consult your doctor.

As for all corticosteroids, indiscriminate use of the product may mask symptoms of clinical interest.

Talk to your doctor or pharmacist before using Advantan:

- if the subject has skin conditions accompanied by bacterial or fungal infections which require treatment with a specific therapy;
- if the subject has local skin infections, because they might worsen with the use of corticosteroids applied to the skin;
- if you suffer from glaucoma, tell your doctor. As is known for corticosteroids which have effects on the whole body (systemic corticosteroids), glaucoma can appear even with the use of corticosteroids applied locally (topical corticosteroids) to the area to be treated (for example, after the use of excessive doses or on extended areas for prolonged periods, with occlusive bandaging or after application to the skin around the eyes).
- if you use Advantan to treat large areas of the body, or for prolonged periods of time, in particular under occlusive bandaging, the duration of treatment must be as short as possible, since the risk of absorption and the appearance systemic unwanted effects cannot be completely excluded.

Advantan must not come into contact with the eyes, open wounds or mucous membranes.

Treatment with occlusive bandaging must be avoided unless indicated. Note that nappies as well as the intertriginous areas can act as occlusive bandages.

After application of Advantan 0.1% ointment to 60% of the body surface under occlusive bandages for 22 hours, suppression of plasma cortisol levels and an influence on the circadian rhythm were noted in healthy adult volunteers, so it is necessary that in such situations treatment must be administered for the minimum indispensable time.

Contact your doctor if you experience blurred vision or other visual disturbances.

If Advantan 0.1% Ointment is applied to the anal or genital areas, some of its ingredients may cause damage to latex products such as condoms or diaphragms. Therefore, these may no longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist, if you require more information.

Children

Do not use Advantan with nappies/diapers since the nappy can act as an occlusive bandage. In fact, Advantan must not be used under occlusive bandages.

The doctor must carefully assess the risk/benefit ratio of the treatment for babies between the ages of 4 months and 3 years.

Other medicines and Advantan

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

No interactions with other medicines are known, to date.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. *Pregnancy*

As a general rule, in pregnant women, the use of corticosteroids in the first trimester must be avoided. In particular, during pregnancy, the treatment of large areas of skin, prolonged use, or occlusive bandages must be avoided (see 'Warnings and precautions').

Some epidemiological studies suggest that there could be an increased albeit limited risk of cleft palate (malformation of the palate) in newborns of women treated with systemic glucocorticosteroids during the first trimester of pregnancy.

Consequently, during pregnancy, Advantan must be used only if, in the physician's opinion, the benefits outweigh the risks.

Breast-feeding

It is not known if topical administration of Advantan can lead to sufficient systemic absorption of methylprednisolone aceponate to determine detectable quantities in the breast milk.

For this reason, care must be taken when Advantan is administered to breastfeeding women.

The breasts of breastfeeding women must not be treated.

During breastfeeding, treatment of large areas of skin, prolonged use, or occlusive bandages, must be avoided (see 'Warnings and precautions').

Fertility

No information is available on the influence of methylprednisolone aceponate on fertility.

Driving and using machines

Advantan does not influence the ability to drive or use machinery.

3. How to use Advantan

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by a doctor, Advantan must be applied to the affected area of skin in a thin layer, with gentle massage, once a day.

If extensive areas of skin are to be treated, the duration of treatment should be suitably limited by the doctor.

The duration of treatment must not exceed 12 weeks in adults and 4 weeks in children.

Use in children

The safety of Advantan in newborns under 4 months has not been established.

If you use more Advantan than you should

If cases of skin atrophy (more or less marked thinning of the skin and the subcutaneous tissue) should occur, due to the use of Advantan in quantities greater than those needed, the treatment must be suspended.

Normally the symptoms regress in 10 - 14 days.

The results of the acute toxicity studies with methylprednisolone aceponate gave no indications of any risk of acute intoxication after single cutaneous application of an excessive quantity (application on a large surface area in conditions that favour absorption) or of accidental ingestion of Advantan ointment.

If you should accidentally administer/ingest an excessive quantity of Advantan, inform your doctor immediately or go to the nearest hospital.

IF YOU HAVE ANY DOUBTS ABOUT THE USE OF ADVANTAN, ASK YOUR DOCTOR OR PHARMACIST.

If you forget to use Advantan

Do not take a double dose to make up for a forgotten dose.

If you stop using Advantan

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The assessment of side effects is generally based on the following frequency conventions:

Very common: present in more than 1 user in 10

Common: present in 1 to 10 users in 100

Not common: present in 1 to 10 users in 1000

Rare: present in 1 to 10 users in 10,000

Very rare: present in more than 1 user in 10,000

Unknown: the frequency cannot be defined on the basis of the data available.

Systemic disorders and conditions affecting the administration site:

- *Common*: burning, itching.
- *Not common*: dryness, erythema, blisters, irritation, eczema, peripheral oedema.
- *Unknown*: folliculitis (inflammation of the piliferous follicles), hypertrichosis (increase in body hair).

Immune system disorders:

- *Unknown*: allergy to the medicinal product.

Skin and subcutaneous tissue disorders:

- *Not common*: skin atrophy, ecchymosis, impetigo (superficial skin infection), greasy skin.
- *Unknown*: teleangiectasia (dermatosis with characteristic ulcers), stretch marks, perioral dermatitis (inflammation of the skin around the mouth), skin discoloration, allergic skin reaction, acne.

Systemic effects due to absorption can occur when topical corticosteroid-based preparations are applied.

Eye disorders

- *Not common*: Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Malta ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Advantan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after *Scad.* (EXP). The expiry date refers to the last day of that month.

The expiry date indicated refers to unopened packages of the product, correctly stored.

Store at a temperature no higher than 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Advantan contains

- The active substance is methylprednisolone aceponate.
- 1 g of ointment contains 1mg methylprednisolone aceponate (0.1%).
- The other ingredients are white vaseline, liquid paraffin, white wax, high molecular weight aliphatic esters, purified water.

What Advantan looks like and contents of the pack

Ointment, 20 g tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

LEO Pharma A/S, Industriparken 55, 2750 Ballerup, Denmark

Manufacturer

LEO Pharma Manufacturing Italy S.r.l., Via E. Schering 21 - 20090 Segrate (Milan), Italy

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