



Advantan® Cream

Package leaflet: Information for the patient

This is a medicament

- ▶ A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ▶ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- ▶ Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists

Advantan 0.1% Cream

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

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1. What Advantan 0.1% Cream is and what it is used for

Advantan 0.1% Cream contains the active substance methylprednisolone aceponate. Advantan 0.1% Cream is a medicine for the treatment of inflammation (a corticosteroid), intended for application to the skin.

Advantan 0.1% Cream is used in endogenous eczema (atopic dermatitis, neurodermatitis), contact eczema, degenerative eczema, dyshidrotic eczema, nummular eczema, unclassified eczema and eczema in children.

2. What you need to know before you use Advantan 0.1% Cream

Do not use Advantan 0.1% Cream

- ▶ if you are allergic to methylprednisolone aceponate or any of the other ingredients of this medicine (listed in section 6).
- ▶ if you have the following disorders:
 - ▷ tuberculous or syphilitic processes
 - ▷ viral infections (e.g. herpes, chickenpox (varicella))
 - ▷ red or pink-coloured inflammation of the skin (rosacea)
 - ▷ inflammation of the skin around the mouth (perioral dermatitis)
 - ▷ ulcers
 - ▷ common acne

- ▷ thinning of the skin (atrophic skin diseases)
- ▷ vaccine reactions in the treatment area
- ▷ skin infections caused by bacteria or fungi (see Warnings and precautions)

Warnings and precautions

Talk to your doctor or pharmacist before using Advantan 0.1% Cream.

Take special precautions when using Advantan 0.1% Cream if your doctor has diagnosed an accompanying skin infection caused by bacteria and/or fungi. In this case, you must also use the medicines prescribed for this infection; otherwise, your infection may get worse.

Anti-inflammatory agents (corticosteroids), to which methylprednisolone aceponate, the active substance in Advantan 0.1% Cream, also belongs, have a potent effect on the body. It is therefore not advisable to use Advantan 0.1% Cream on large skin areas or over prolonged periods, as this significantly increases the risk of side effects.

To reduce the risk of side effects:

- ▶ Use Advantan 0.1% Cream as sparingly as possible, especially in children.
- ▶ Use Advantan 0.1% Cream only for as long as is absolutely necessary to treat your skin disease.
- ▶ Advantan 0.1% Cream must not get into the eyes, deep open wounds or onto the mucous membranes.
- ▶ Advantan 0.1% Cream should not be used under airtight or waterproof materials, unless prescribed by your doctor. For example, this includes bandages, tight-fitting bandages or tight clothing and nappies.

Local skin infections may possibly be made worse by the external use of corticosteroids.

As with all other corticosteroids, the use of Advantan 0.1% Cream can mask the signs (symptoms) of disorders other than those indicated and prevent correct diagnosis and treatment.

As is known with internally administered (systemic) corticosteroids, glaucoma may also develop after external use of corticosteroids (e.g. after high-dose or extensive use for prolonged periods, after use of occlusive dressings or after use on the skin near the eye).

Children and adolescents

Use as little Advantan 0.1% Cream as needed to avoid side effects. Advantan 0.1% Cream should not be used under airtight and waterproof materials, e.g. nappies.

Advantan 0.1% Cream is not recommended for use in children under 3 years of age due to the lack of safety data.

Other medicines and Advantan 0.1% Cream

To date, there are no known interactions between Advantan 0.1% Cream and other medicines.

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

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.

There are insufficient data for the use of Advantan 0.1% Cream in pregnant women. In animal trials, the active substance of Advantan 0.1% Cream (methylprednisolone aceponate) showed a harmful effect on the foetus.

Data from large-scale (epidemiological) studies suggest that, after treatment with systemic corticosteroids (internal use) during the first 3 months of pregnancy, there is a possible risk that cleft palate may occur in newborn infants.

In general, preparations containing corticosteroids for external application should not be used during the first 3 months of pregnancy. Pregnant and breast-feeding women should use Advantan 0.1% Cream only after a careful risk-benefit assessment by the doctor.

Advantan 0.1% Cream must not be applied to relatively large areas, for prolonged periods of time or be covered by dressings (occlusive conditions), as this could result in exposure in the unborn child. During the breast-feeding period, Advantan 0.1% Cream must not be used in the breast area. Especially during the breast-feeding period, Advantan 0.1% Cream must not be applied to relatively large areas, for prolonged periods of time or be covered by dressings (occlusive conditions).

No data are available on the effect of methylprednisolone aceponate on fertility.

Driving and using machines

Advantan 0.1% Cream has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Advantan 0.1% Cream

Advantan 0.1% Cream contains the other ingredients cetostearyl alcohol and butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis). Butylated hydroxytoluene may also cause irritation to the eyes or mucous membranes.

3. How to use Advantan 0.1% Cream

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 the doctor, Advantan 0.1% Cream is applied once daily.

- ▶ Advantan 0.1 % Cream is thinly applied to the affected skin areas and gently rubbed in.
- ▶ The duration of use should generally not exceed 6 weeks in adults and 3 weeks in children over 3 years of age.
- ▶ If the skin dries out too much during prolonged use of Advantan 0.1% Cream, a switch should be made to a preparation with a higher fat content (Advantan ointment or fatty ointment).

If you have the impression that the effect of Advantan 0.1% Cream is too strong or too weak, talk to your doctor or pharmacist.

Use in children and adolescents

Advantan 0.1% Cream is not recommended for use in children under 3 years of age due to the lack of safety data.

For the use of Advantan 0.1% Cream in children over 3 years of age, no adjustment in dosage is required. In general, the duration of use in children should not exceed 3 weeks.

If you use more Advantan 0.1% Cream than you should

Results from studies with methylprednisolone aceponate, the active pharmaceutical ingredient of Advantan 0.1% Cream, show that there is no risk of acute intoxication after single application of an overdose to the skin (= extensive use under conditions that favour absorption into the skin) or accidental ingestion.

If you forget to use Advantan 0.1% Cream

If you have forgotten the previous dose, do not apply more Advantan 0.1% Cream than you normally would but continue the treatment as discussed with your doctor.

If you stop using Advantan 0.1% Cream

If you stop treatment with Advantan 0.1% Cream too soon, your symptoms may get worse. For this reason, talk to your doctor before you interrupt or stop treatment on your own initiative.

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 everybody gets them.

The following frequency data are used for evaluating side effects:

Common: may affect up to 1 in 10 patients treated

Uncommon: may affect up to 1 in 100 patients treated

Rare: may affect up to 1 in 1,000 patients treated

Not known: cannot be estimated from the available data.

Common: burning and itching may occur at the administration site during treatment with Advantan 0.1% Cream.

Uncommon: hypersensitivity to the active substance and local side effects may occur, such as dry skin, skin redness, blisters, inflammation of the hair follicles (folliculitis), rash and abnormal skin sensations (paraesthesia).

Rare: a pustular rash (pyodermitis), skin fissures, dilation of blood vessels in the skin (telangiectasia), skin thinning (skin atrophy), fungal skin infection, and acne may occur, as well as cellulitis, oedema and skin irritation within the area of the application site.

Frequency not known: stretch marks (striae), increased hair growth (hypertrichosis), inflammation of the skin around the mouth (perioral dermatitis), skin discoloration and allergic skin reactions may occur. Internal (systemic) effects may occur due to uptake into the body (absorption) after external use of medicines containing corticosteroids.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Advantan 0.1% Cream

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 container and carton after «EXP». The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C.

Note on shelf life after opening

After opening the tube, Advantan 0.1% Cream has a shelf life of 3 months.

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 0.1% Cream contains

The active substance is methylprednisolone aceponate.

1 g cream contains 1 mg methylprednisolone aceponate (0.1%).

The other ingredients are:

- ▶ Benzyl alcohol,
- ▶ Butylated hydroxytoluene (Ph.Eur.),
- ▶ Cetostearyl alcohol (Ph.Eur.),
- ▶ Decyl oleate, purified water,
- ▶ Glycerol 85%,
- ▶ Glycerol monostearate 40-55,
- ▶ Glycerol trialkanoate (C₈-C₁₈),
- ▶ Hard fat, macrogol stearate 2000,
- ▶ Sodium edetate (Ph.Eur.).

What Advantan 0.1% Cream looks like and contents of the pack

Advantan 0.1% Cream is a white to yellowish translucent emulsion. Advantan 0.1% Cream is available in tubes of 15 g, 20 g, 25 g, 50 g and 100 g.

Manufacturer

Bayer HealthCare Manufacturing S.r.l.,
Via E. Schering 21 – 20090 Segrate (Milan) – Italy

Marketing Authorization Holder

Bayer Pharma AG, Berlin, Germany.

This leaflet was last revised in January, 2014.