

Package leaflet

Package leaflet - Advantan lipid DE - Zip code change – 6-2

Package leaflet: Information for patients

Advantan® 0.1% fatty ointment, ointment

Methylprednisolone aceponate

Read the entire package leaflet carefully before you start using this medicine, because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. See section 4.

What is in this package leaflet

1. What is Advantan 0.1% fatty ointment and what is it used for?
2. What should you consider before using Advantan 0.1% fatty ointment?
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6. Contents of the pack and other information

1. What is Advantan 0.1% fatty ointment and what is it used for?

Advantan 0.1% fatty ointment contains the active ingredient methylprednisolone aceponate. Advantan 0.1% fatty ointment is a medication for the treatment of inflammations (a corticosteroid) intended for application on the skin.

Advantan 0.1% fatty ointment is used for endogenous eczema (atopic dermatitis, neurodermatitis), contact eczema, degenerative eczema, and nummular eczema.

2. What should you consider before using Advantan 0.1% fatty ointment?

Advantan 0.1% fatty ointment must not be used, 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 conditions:

- tuberculous or syphilitic processes
- viral infections (e.g., herpes, chickenpox (varicella))
- red or rosy-colored inflammation of the skin (rosacea)
- inflammations of the skin around the mouth (perioral dermatitis)
- ulcers
- common acne

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

Warnings and precautions

Please talk to your doctor or pharmacist before using Advantan 0.1% fatty ointment.

Take special precautions when using Advantan 0.1% fatty ointment if your doctor has identified a concurrent skin infection caused by bacteria and/or fungi. In this case, you must also use the medications prescribed for this infection, otherwise your infection may worsen.

Anti-inflammatory drugs (corticosteroids), which include the active ingredient methylprednisolone aceponate in Advantan 0.1% fatty ointment, have a strong effect on the body. Therefore, it is advised against using Advantan 0.1% fatty ointment on large areas of skin or for prolonged periods, as this significantly increases the risk of side effects.

To reduce the risk of side effects:

- Use Advantan 0.1% fatty ointment as sparingly as possible, especially in children.
- Use Advantan 0.1% fatty ointment only as long as absolutely necessary to treat your skin condition.
- Advantan 0.1% fatty ointment must not come into contact with the eyes, deep open wounds, or mucous membranes.
- Advantan 0.1% fatty ointment should not be used under airtight and waterproof materials unless prescribed by your doctor. This includes bandages, tight-fitting dressings, or tight clothing, as well as diapers.

Local skin infections may potentially be exacerbated by the topical application of corticosteroids.

As with all other corticosteroids, the use of Advantan 0.1% fatty ointment for conditions other than those intended can mask their signs (symptoms) and hinder correct diagnosis and therapy.

As known from systemically administered corticosteroids, glaucoma can also develop after topical application of corticosteroids (e.g., after high-dose or large-area application over a long period, after use of occlusive dressings, or after application near the eyes).

If you experience blurred vision or other visual disturbances, contact your doctor.

When using Advantan 0.1% fatty ointment in the anal or genital area, some of its other ingredients may damage 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 need more information.

Children and adolescents

Use as little Advantan 0.1% fatty ointment as necessary to avoid side effects. Advantan 0.1% fatty ointment should not be used under airtight and waterproof materials, such as diapers.

Use of Advantan 0.1% fatty ointment with other medications

Interactions of Advantan 0.1% fatty ointment with other medications are not known so far.

Inform your doctor or pharmacist if you are taking/using other medicines, have recently taken/used other medicines, or intend to take/use other medicines.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

There is insufficient data on the use of Advantan 0.1% fatty ointment in pregnant women. In animal studies, the active ingredient of Advantan 0.1% fatty ointment (methylprednisolone aceponate) showed teratogenic effects.

Data from large-scale (epidemiological) studies suggest that treatment with systemic corticosteroids (internal use) during the first 3 months of pregnancy may pose a risk for the occurrence of cleft palate in newborns.

During the first 3 months of pregnancy, corticosteroid-containing preparations for external use should generally not be applied. Pregnant and breastfeeding women should use Advantan 0.1% fatty ointment only after careful risk-benefit assessment by the doctor.

Advantan 0.1% fatty ointment should not be applied to large areas, for prolonged periods, or under occlusive conditions, as this could pose a risk to the unborn child.

During the breastfeeding period, Advantan 0.1% fatty ointment should not be applied to the breast area. Above all, during the breastfeeding period, no application of Advantan 0.1% fatty ointment on large areas, for prolonged periods, or under occlusive conditions should occur.

There is no data available on the influence of methylprednisolone aceponate on fertility.

Driving and using machines

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

Advantan 0.1% fatty ointment contains paraffin and vaseline

When treating with Advantan 0.1% fatty ointment in the genital or anal area, the other ingredients paraffin and vaseline may reduce the tensile strength of latex condoms and thus impair the safety of the condoms.

3. How to use Advantan 0.1% fatty ointment?

Always use this medicine exactly as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, Advantan 0.1% fatty ointment is applied once daily.

- Advantan 0.1% fatty ointment is applied thinly to the affected skin areas and gently rubbed in.
- The duration of use should generally not exceed 6 weeks in adults.

Please talk to your doctor or pharmacist if you have the impression that the effect of Advantan 0.1% fatty ointment is too strong or too weak.

Use in children and adolescents

For the use of Advantan 0.1% fatty ointment in children and adolescents, no dosage adjustment is necessary. The duration of use should generally not exceed 3 weeks in infants, children, and adolescents.

If you have applied more Advantan 0.1% fatty ointment than you should have

Results from studies with methylprednisolone aceponate, the active pharmaceutical ingredient of Advantan 0.1% fatty ointment, show that there is no acute risk of poisoning after a single overdose application to the skin (= large-area application under favorable conditions for absorption into the skin) or accidental ingestion.

If you forget to apply Advantan 0.1% fatty ointment

If you forget the previous application, do not apply a larger amount of Advantan 0.1% fatty ointment than usual, but continue the treatment as discussed with your doctor.

If you stop using Advantan 0.1% fatty ointment

If you prematurely stop treatment with Advantan 0.1% fatty ointment, the condition may worsen. Therefore, talk to your doctor before interrupting or ending the treatment on your own.

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

4. What side effects are possible?

Like all medicines, this medicine can have side effects, although not everybody gets them.

The following frequency categories are used to evaluate side effects:

Common: may affect up to 1 in 10 treated people

Occasionally: may affect up to 1 in 100 treated individuals

Not known: Frequency cannot be estimated from the available data

Commonly, burning and folliculitis (inflammation of hair follicles) may occur at the site of application during treatment with Advantan 0.1% fatty ointment.

Occasionally, skin fissures, dilation of skin vessels (telangiectasia), and local accompanying symptoms such as pustules, blisters, itching, pain, skin redness, and papules may occur.

Frequency not known: Hypersensitivity to the active substance, acne, thinning of the skin (skin atrophy), formation of stretch marks (striae), increased hair growth (hypertrichosis), inflammation of the skin around the mouth (perioral dermatitis), skin discoloration, and allergic skin reactions may occur.

Systemic effects may occur due to absorption into the body following external application of corticosteroid-containing medications.

Blurred vision.

Reporting of side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept.

Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Advantan 0.1% fatty ointment?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the container and outer packaging after 'Use by'. The expiry date refers to the last day of that month.

Storage conditions

No special storage conditions are required for this medicine.

Note on shelf life after opening

After opening the tube, Advantan 0.1% fatty ointment is stable for 3 months.

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of the medicine when you no longer use it. This helps protect the environment.

6. Contents of the packs and further information

What Advantan 0.1% fatty ointment contains

- The active ingredient is: Methylprednisolone aceponate.
1 g of ointment contains 1 mg of methylprednisolone aceponate (0.1%).
- The other ingredients are:
Liquid paraffin, hydrogenated castor oil, microcrystalline hydrocarbons (C40-C60), white petrolatum.

What Advantan 0.1% fatty ointment looks like and contents of the pack

Advantan 0.1% fatty ointment is a white to yellowish translucent ointment.

Advantan 0.1% fatty ointment is available in tubes of 15 g, 25 g, 50 g, and 100 g of ointment.

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