

## Instructions for use: Information for patients

Advantan 0,1 % cream  
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

### What is in this package leaflet

1. What is Advantan 0,1 % cream and what is it used for?
2. What should you consider before using Advantan 0,1 % cream?
3. How is Advantan 0,1 % cream to be used?
4. What side effects are possible?
5. How should Advantan 0,1 % cream be stored?
6. Contents of the package and further information

#### 1. What is Advantan 0,1 % cream and what is it used for?

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

Advantan 0.1% cream is used for endogenous eczema (atopic dermatitis, neurodermatitis), contact eczema, degenerative eczema, and nummular eczema. Eczema and nummular eczema applied.

#### 2. What should you know before using Advantan 0% cream? Advantan 0

,1% cream must not be used % cream must not be used

- you are allergic to methylprednisolone aceponate or any of the other ingredients listed in section 6. mentioned other ingredients of this medicine. if you have the following conditions: tuberculous or syphilitic processes
- 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 % cream.

Take special precautions when using Advantan 0,1 % cream if your doctor has diagnosed a concomitant skin infection caused by bacteria and/or fungi. 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% cream, have a strong effect on the body. It is therefore advised against using Advantan 0,1 % cream on large areas of skin or for a prolonged period, 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 as long as absolutely necessary to treat your skin condition. Advantan 0
- ,1% cream must not come into contact with the eyes, deep open wounds, or mucous membranes. Advantan 0
- ,1% cream should not be used under airtight and waterproof materials unless prescribed by your doctor. This includes bandages, tight-fitting dressings % cream should not be used under air- and watertight materials if it tight clothing as well as diapers. or tight clothing as well as diapers.

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

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

As known from internally administered (systemic) corticosteroids, glaucoma can also develop after topical application of corticosteroids (e.g., after high doses or extensive application over a long period, after use of occlusive dressings or after application on skin near the eyes).

## Children and adolescents

Use as little Advantan 0,1 % cream as necessary to avoid side effects. Advantan 0.1% cream should not be used under airtight and watertight materials, e.g., diapers.

Advantan 0,1 % cream is not recommended for use in children under 3 years due to the lack of safety data.

Use of Advantan 0,1 % cream together with other medications

Interactions Interactions of Advantan 0,1% cream with other medications are not known so far.

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

### 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 medication. There is insufficient data on the use of Advantan 0.1% cream in pregnant women. In animal studies, the active ingredient of Advantan 0.1% cream (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.

Pregnant and breastfeeding women should use Advantan. Oeating of cleft palates in newborns exists.

% cream only after careful risk-benefit assessment by the doctor. Advantan 0,1 % Cruse only after careful risk-benefit assessment by the physician.

Advantan 0,1 % cream must not be applied to large areas, for prolonged periods, or under occlusive conditions, as this could lead to a burden on the unborn child. During the breastfeeding period, Advantan 0,1 % cream must not be applied to the breast area. In particular, during the breastfeeding period, no application of Advantan 0,1 % cream on large areas, for prolonged periods or under occlusive conditions should occur.

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

### Ability to drive and use machines

Advantan 0,1 % cream contains Important information about certain other ingredients of

Advantan 0 other excipients of  
% cream The other ingredients contained in Advantan 0 ,1

The in Advantan 03. How to use Advantan 0 oil and butylated hydroxytoluene can cause localized skin irritations (e.g., contact dermatitis). Butylated hydroxytoluene can also cause irritation of the eyes and mucous membranes.

3. Always use this medicine exactly as agreed with your doctor or % cream to apply?

Apply always take this medicine exactly as agreed with your doctor or Consult your pharmacist. Ask 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 applied thinly 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.

If during prolonged use of Advantan 0,1 % cream the skin becomes too dry, a preparation with a higher fat content (Advantan ointment or fatty ointment) should be used.

Please talk to your doctor or pharmacist if you have the impression that the effect of Advantan 0,1 % cream is too strong or too weak.

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, no dosage adjustment is necessary. In general, the duration of use in children should not exceed 3 weeks.

If you have applied a larger amount of Advantan 0,1 % cream than you should have used more than you should have

area application under favorable conditions for absorption into the skin) or accidental ingestion. If you have forgotten to apply Advantan 0

If you use Advantan 0% cream If you have forgotten the previous application, do not apply a

larger amount of Advantan 0 larger quantity Advantan 0% cream than usual, but continue the treatment as discussed with your doctor. If you have forgotten to apply Advantan 0

If you use Advantan 0,1 % cream discontinue

If you stop the treatment with Advantan 0,1 % cream prematurely, it may lead to a worsening of the condition. Therefore, talk to your doctor before interrupting or stopping the treatment on your own.

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

#### 4. What side effects are possible?

Like all medicines, this medicine can have side effects, but not everyone will experience them.

The following frequency information is used to evaluate side effects: Common: may

affect up to 1 in 10 treated. Occasionally: may

affect to in up to 1 in 100 treated patients.

Rare: may up to in up to 1 in 1000 treated patients.

Unknown: Frequency cannot be estimated from the available data.

Commonly, burning and itching at the site of administration may occur during treatment with Advantan 0.1% cream.

Occasionally, hypersensitivity to the active ingredient and local accompanying symptoms such as dry skin, skin redness, blisters, folliculitis, rash, and skin sensations (paresthesia) may occur.

Rarely, pustular rash (pyoderma), skin fissures, dilation of skin vessels (telangiectasia), skin thinning (skin atrophy), fungal skin infection, acne, and cellulitis, edema, and skin irritation at the site of administration may occur.

Unknown frequency: It may lead to striae, increased hair growth (hypertrichosis), inflammation of the skin around the mouth (perioral dermatitis), skin discoloration, and allergic skin reactions.

Systemic effects may occur due to absorption into the body (resorption) after external application of corticosteroid-containing medications.

#### 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 package 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](http://www.bfarm.de).

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

#### 5. How should Advantan 0,1 % cream be stored?

Keep this medicine out of the reach of children inaccessible.

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

#### Storage conditions

Do not store above 25 °C.

#### Note on shelf life after opening

After opening the tube, Advantan 0,1 % cream is stable for 3 months. durable.

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

## 6. Contents of the packs and further information

What Advantan 0,1 % cream contains

The active ingredient is methylprednisolone aceponate.

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

The other ingredients are:

- benzyl alcohol,
- Butylhydroxytoluene (Ph. Eur.),
- Cetylstearyl alcohol (Ph. Eur.),
- Decyloleate, purified water,
- Glycerol 85%,
- Glycerol monostearate 40-55,
- Glycerol triacanoate (C<sub>8</sub>-C<sub>18</sub>),
- Hard fat, Macrogol stearate 2000
- Disodium edetate (Ph. Eur.).

What Advantan 0,1 % cream looks like and contents of the package

Advantan 0,1 % cream is a white to yellowish opaque emulsion. Advantan 0.1% cream is available in tubes of 15 g, 25 g, 50 g, and 100 g.

Pharmaceutical entrepreneur

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