

Package leaflet: Information for the patient

Advantan Cream 0.1% w/w
Advantan Ointment 0.1% w/w
Advantan Fatty Ointment 0.1% w/w

Methylprednisolone aceponate (MPA)

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. 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 is and what it is used for
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1. What Advantan is and what it is used for

Advantan is an anti-inflammatory medicine (a corticosteroid) which is intended to be used on the skin.

Advantan reduces the inflammation and allergic reaction of the skin. Therefore it lessens redness (erythema), fluid build-up (oedema) and fluid oozing from the inflamed skin. It also relieves the itchiness, burning sensation or pain you may feel.

Advantan is used for the treatment of skin conditions which are sensitive to corticosteroids.

2. What you need to know before you use Advantan

Do not use Advantan

- if you are allergic (hypersensitive) to the active substance methylprednisolone aceponate (MPA) or to any of the other ingredients of Advantan (see also section 6. Contents of the pack and other information)
- if pre-existing eczema or rash has become infected
- on skin areas affected by a skin inflammation that is red/rosy in colour (rosacea), ulcers, inflamed diseases of the sebaceous glands (acne vulgaris) or skin folds, groin or under

the arm pits (intertrigo acne), or skin diseases accompanied by a thinning of the skin (atrophic skin diseases)

- on skin that is weeping
- on skin areas that show a vaccination reaction i.e. that are red or inflamed after being given a vaccine
- on specific skin inflammation in the area of the upper lip and chin (perioral dermatitis)
- on bacterial, viral or fungal skin infections (unless treated accordingly with a special medicine)
- on children under 4 months.

Warnings and precautions

Talk to your doctor before using Advantan

If your doctor diagnoses that your skin disease is accompanied by bacterial or fungal infections, additional specific therapy is required. Talk to your doctor if the infection spreads or gets worse.

Anti-inflammatory medicines (corticosteroids) like the active substance methylprednisolone aceponate in Advantan show strong effects on the body. It is not recommended to use Advantan on large areas of the body or for prolonged periods of time as this will significantly increase the risk of side effects.

To reduce the risk of side effects:

- use as little as possible, especially in children
- use only for as long as is absolutely necessary to relieve the skin condition
- you should not get Advantan into your eyes or mouth, open wound or on mucosal surfaces (e.g. the anal and genital area)
- you should not use Advantan on large body surfaces (more than 40 % of your body surface)
- you should not use Advantan under air- and watertight materials including bandages, poorly breathable dressings, clothing or nappies

If you use Advantan for other diseases than prescribed, you may cover the symptoms and hinder the right diagnosis and therapy.

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

If Advantan 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

Use as little as possible, especially in children. You should not use Advantan under nappies. Advantan may be used in children between 4 months and 3 years of age if it has been prescribed for them by their doctor.

Other medicines and Advantan

Interactions of Advantan with other medicines are not known so far.

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

Pregnancy and breast-feeding

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

As a general rule, topical preparations containing corticosteroids should not be applied during the first three months of pregnancy. Large-area, prolonged use or use of air- and water-proof dressings should be avoided in pregnancy.

If your doctor recommends the use of Advantan while breast-feeding, do not apply the medicine on the breasts. Do not bring your baby into contact with the treated areas. Large-area, prolonged use or use of air- and water-proof dressings should be avoided while breastfeeding.

Driving and using machines

Using Advantan does not affect the ability to drive or use machines.

Advantan Cream contains butyl hydroxytoluene (E321) and cetylstearyl alcohol

Advantan Cream contains butyl hydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes, and cetylstearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

Advantan cream contains benzyl alcohol

This medicine contains 1.0 g benzyl alcohol in each 100 g. Benzyl alcohol may cause allergic reactions and/or mild local irritation.

3. How to use Advantan

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

If not prescribed otherwise by your doctor, the general dosage is as follows:

- apply Advantan thinly once per day to the affected areas of skin;
- always keep the treatment period as short as possible. The duration of use should not exceed 12 weeks in adults and 4 weeks in children
- if your skin dries out excessively using Advantan Cream, ask your doctor about switching to one of the formulations with a higher fat content (Advantan Ointment or Advantan Fatty Ointment).
- if you have an impression that the effect of Advantan is too strong or too weak, talk to your doctor or pharmacist.

Use in children

Advantan is not recommended for use in children under 4 months of age, due to a lack of data on safety.

If you use more Advantan than you should

No risk is to be expected from a one-time overdose (too large amount or too large skin area).

If you forget to use Advantan

Do not use the double amount the next time, but continue the use as prescribed by your doctor or described in the package leaflet.

If you stop using Advantan

Please contact your doctor or pharmacist before you stop the treatment with Advantan. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Advantan can cause side effects, although not everybody gets them.

The assessment of the side effects is based on the following frequencies:

Common: less than 1 in 10, but more than 1 in 100 patients

Uncommon: less than 1 in 100, but more than 1 in 1,000 patients

Rare: less than 1 in 1000, but more than in 10,000

Very rare: less than 1 in 10,000

Not known: the frequency cannot be estimated from the available information

Cream

Common:

- a burning sensation and itch at the site of application

Uncommon:

- dryness, redness (erythema), blisters, hair follicle inflammation (folliculitis), rash or tingling at the site of application
- allergic skin reaction (contact dermatitis)

Rare:

- skin infection, swelling or irritation at the site of application
- fungal skin infection
- skin infection producing pus, skin cracks, swelling of the small blood vessels in the skin, thinning of the skin (atrophy), acne

Not known:

- increased hair growth
- stretch marks, specific skin inflammation in the area of the upper lip and chin (perioral dermatitis), skin discolouration, allergic skin reaction (contact dermatitis)
- blurred vision

Ointment

Common:

- a burning sensation and itch at the site of application

Uncommon:

- redness (erythema), dryness, blisters, irritation or eczema at the site of application, swelling
- thinning of the skin (atrophy), bruising, bacterial skin infection (impetigo), greasy skin

Not known:

- increased hair growth, hair follicle inflammation (folliculitis) at the site of application
- allergy
- acne, swelling of the small blood vessels in the skin, stretch marks, specific skin inflammation in the area of the upper lip and chin (perioral dermatitis), skin discolouration, allergic skin reaction (contact dermatitis)
- blurred vision

Fatty Ointment

Common:

- a burning sensation and hair follicle inflammation (folliculitis) at the site of application

Uncommon:

- pimples with pus, blisters, itch, pain, redness (erythema), or pimples without pus at the site of application,
- skin cracks, swelling of the small blood vessels in the skin

Not known:

- increased hair growth,
- allergy
- acne, thinning of the skin (atrophy), stretch marks, specific skin inflammation in the area of the upper lip and chin (perioral dermatitis), skin discolouration, allergic skin reaction
- blurred vision

The use of anti-inflammatory medicines, so-called corticosteroids (like the active substance in Advantan) on the skin can result in the following untoward effects:

- thinning of the skin (atrophy)
- stretch marks
- hair follicle inflammation (folliculitis) at the site of application
- increased body hair growth
 - swelling of the small blood vessels in the skin
- specific skin inflammation in the area of the upper lip and chin (perioral dermatitis)
- changes in skin colour
- allergic skin reaction (contact dermatitis).

In rare cases side effects can occur not only at the treatment site but also in completely different areas of the body. This happens if the active substance (a corticosteroid) is

absorbed into the body through the skin. This can, for example, increase the pressure in the eye (glaucoma).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Advantan

Keep these medicines out of the sight and reach of children.

Advantan Cream & Ointment

Store below 25°C.

Advantan Fatty Ointment

Store below 30°C.

Do not use these medicines after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

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

The active substance is: methylprednisolone aceponate (MPA).

Each 1g cream, ointment, fatty ointment contains methylprednisolone aceponate 1mg (0.1%).

The other ingredients are:

Cream

decyl oleate, glycerol monostearate, cetylstearyl alcohol, hard fat, glycerol fatty acid triesters (Softisan 378), polyoxyl-40-stearate, glycerol 85 %, disodium edetate, benzyl alcohol, butyl hydroxytoluene (E321), purified water

Ointment

dehymuls E (dicocoyl pentaerythryl distearyl citrate, sorbitan sesquioleate, beeswax, aluminium stearates), white soft paraffin, paraffin liquid, white wax, purified water

Fatty Ointment

white soft paraffin, paraffin liquid, microcrystalline wax, hydrogenated castor oil

What Advantan looks like and contents of the pack

The cream is white to yellowish and opaque. The ointment is white to yellowish and opaque. The fatty ointment is a translucent white to yellowish ointment. Advantan is available in tubes of 5g, 10g, 15g, 30g, and 50g. Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

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