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.

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).

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)

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)

**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

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.
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 tri-esters (Softisan 378), polyoxyyl-40-steareate, glycerol 85 %, disodium edetate, benzyl alcohol, butyl hydroxytoluene (E321), purified water

**Ointment**
dehymuls E (dicocoyl pentaerythrityl 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**
Marketing Authorization Holder:
This leaflet was last revised in December 2014.