**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S4**

# ADVANTAN CREAM 0,1 % w/w

# ADVANTAN FATTY OINTMENT 0,1 % w/w

# ADVANTAN OINTMENT 0,1 % w/w

**Methylprednisolone aceponate**

**Read all of this leaflet carefully before you start using ADVANTAN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADVANTAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**


1. What ADVANTAN is and what it is used for
2. What you need to know before you use ADVANTAN
3. How to use ADVANTAN
4. Possible side effects
5. How to store ADVANTAN
6. Contents of the pack and other information


## 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 or to any of the other ingredients of Advantan (see also section 6)
- 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)
- during pregnancy.

### 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 60 % of your body surface)
- you should not use Advantan under air- and watertight materials including bandages, poorly breathable dressings, clothing or nappies

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

Some of the ingredients of Advantan 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. If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the medicine without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond

the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

**Children**

Advantan should not be used in the nappy areas in infants and ideally not be used in infants and young children.

**Other medicines and ADVANTAN**

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

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

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**

Blurry or cloudy vision has been reported as a side effect on patients using Advantan. The frequency of this side effect is unknown. If this happens to you, you should not drive or operate machinery.

**Advantan Cream contains butyl hydroxytoluene and cetylstearyl alcohol**

Advantan Cream contains butyl hydroxytoluene, 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

Do not share medicines prescribed for you with any other person.

Always use Advantan exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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.

**If you use more ADVANTAN than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**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**

Don’t stop using Advantan without talking to your doctor first.

**4. Possible side effects**

Advantan can have side effects.

Not all side effects reported for Advantan are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Advantan, please consult your health care provider for advice.

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

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

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

Rare: less than 1 in 1000, but equal to or more than1 in 10 000

Very rare: less than 1 in 10 000

Frequency not known: the frequency cannot be estimated from the available information

**Advantan 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

*Frequency 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
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

**Advantan 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

*Frequency not known*:

- increased hair growth,
- 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
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin

which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

**Advantan 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, lesion, pain
- drug allergy
- *Frequency not known*:
- increased hair growth, 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 (contact dermatitis)
- blurred vision
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via Adcock.AEReports@adcock.com.

By reporting side effects, you can help provide more information on the safety of Advantan.

## 5. How to store ADVANTAN

Store all medicines out of reach of children.

Store below 30 °C.

Do not use these medicines after the expiry date which is stated on the tube and carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

## 6. Contents of the pack and other information

**What ADVANTAN contains**

The active substance is: methylprednisolone aceponate (MPA).

Each 1g cream, ointment, fatty ointment contains methylprednisolone aceponate 1mg (0,1 %).

The other ingredients are:

*Advantan cream*

Benzyl alcohol, butyl hydroxytoluene, caprylic-capric-myristic-stearic triglyceride (softisan 378), cetostearyl alcohol, decyl oleate, disodium edetate, glycerol 85 per cent,

glycerol monostearate 40-55, hard fat, macrogol stearate 40, type I (polyoxyl-40-stearate), water purified.

*Advantan fatty ointment*

White soft paraffin, paraffin, liquid, microcrystalline wax, hydrogenated castor oil.

*Advantan ointment*

Beeswax white, paraffin liquid, dicocoyl pentaerythrityl distearyl citrate + sorbitan sesquioleate + beeswax + aluminum stearates (dehymuls E), paraffin white soft

water purified.

**What ADVANTAN looks like and contents of the pack**

The fatty ointment is a translucent white to yellowish translucent. The ointment is white to yellowish-white opaque. The cream is white opaque.

Advantan is available in aluminium tubes with screw cap polyethylene white (4669) packaging. Tubes of 15g, 20g, 30g, 50g and 100 g are marketed.

**Holder of Certificate of Registration**

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Customer Care: 0860 ADCOCK / 232625

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Advantan fatty ointment: X/13.4.1/386

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|---|---|---|
| NS2 | Advantan cream | 04/13.4.1/1433 |
| NS2 | Advantan fatty ointment | 04/13.4.1/1435 |
| NS2 | Advantan ointment | 04/13.4.1/1434 |

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