

ADVANTAN(R)

OINTMENT, FATTY OINTMENT, CREAM & LOTION

Methylprednisolone aceponate (meth'il -predd -niz-oh -lone ass-epp -on -eight)

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

Please read this leaflet carefully before you start your treatment.

Keep this leaflet.

You may want to read it again.

This leaflet answers some common questions about using Advantan(R). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Advantan(R) against the benefits it is expected to have for you.

If you have any concerns about using Advantan(R), talk to your doctor or pharmacist.

What Advantan(R) is used for

The active ingredient in Advantan(R) belongs to the group of medicines called corticosteroids. The corticosteroid in Advantan(R) is suitable to put on the skin. It is therefore called a topical corticosteroid, which is sometimes shortened to topical steroid.

When Advantan(R) is put on the skin, it relieves the redness, swelling, itching and irritation of the skin in eczema and psoriasis.

Advantan(R) preparations are available only with a doctor's prescription.

Advantan(R) is made up as four different preparations. Each has a distinct look and feel. They are:

- * ointment,
- * fatty ointment,
- * cream and
- * lotion.

The most solid is the fatty ointment; the most runny is the lotion. The ointment and cream are in-between in thickness.

Each preparation is especially suitable in consistency for a particular area of skin or skin condition needing treatment. Your doctor will prescribe the preparation most suitable for you.

The Advantan(R) preparations are medicines and should only be used on skin affected by the conditions described below.

All four Advantan(R) preparations treat eczema.

Advantan(R) ointment, fatty ointment and cream (but NOT lotion) also treat psoriasis.

Eczema is a skin condition with redness, swelling, oozing of fluid, crusting and later scaling. It is often very itchy.

Psoriasis is a skin disorder with raised, rough, reddened areas covered with dry, fine, silvery scales.

Your doctor may have prescribed Advantan(R) for another reason. Discuss this with him/her.

Advantan(R) is not addictive. It is not expected to affect your ability to drive a car or operate machinery.

Before you use Advantan(R)

When you must not use Advantan(R)

Do not use Advantan(R) if you have an allergy to:

- * any medicine containing methylprednisolone aceponate
- * any of the ingredients listed at the end of this leaflet (see Product description).
- * any other similar medicine, that is, topical corticosteroids.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Advantan(R) if in the area of skin you are treating:

you have infection due to

- * tuberculosis (TB) or syphilis
- * a virus such as chicken-pox or shingles
- * a skin reaction following a vaccination.

Do not use Advantan(R) if you have acne, rosacea or perioral dermatitis.

Your doctor will identify these conditions for you.

Do not use Advantan(R)

- * **after the expiry date printed on the pack OR**
- * **if the packaging is torn, doesn't look quite right or shows signs of tampering.**

If the Advantan(R) packaging is damaged or it is past the expiry date, return it to your pharmacist for disposal.

If you have not told your doctor about any of the above, tell him/her before you start using Advantan(R).

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have a known allergy to Advantan(R) or any ingredients listed at the end of this leaflet.

Tell your doctor if you

- * **are pregnant or plan to become pregnant**
- * **are breast-feeding**
- * **plan to breastfeed.**

Your doctor can discuss with you the risks and benefits of using Advantan(R).

Advantan(R) should be used only on the skin. Avoid getting Advantan(R) in your eyes. Do not put Advantan(R) in your mouth. Do not swallow Advantan(R).

Taking other medicines

Tell your doctor or pharmacist if you are on any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Advantan(R).

How to use Advantan(R)

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How to use Advantan(R) preparations

Advantan(R) ointment, fatty ointment and cream

Apply thinly to the affected area of skin.

Advantan(R) lotion

Apply thinly to the affected area of skin and gently rub in.

When to use it

Treatment of eczema

Use Advantan(R) once a day to treat the affected skin.

Treatment of psoriasis

Use Advantan(R) ointment, fatty ointment or cream once or twice a day on the patches of psoriasis.

How long to use it

Usually, treatment with Advantan(R) is for up to 12 (twelve) weeks in adults and 4 (four) weeks in children.

Treatment with Advantan(R) should be for the shortest possible time period, and minimised to only on affected area. This is particularly important when using Advantan under bandages.

This is particularly important when treating large areas, and in children.

Excessive application of topical corticosteroids to large areas of the body for prolonged periods of time can increase the risk of side effects. Discuss this with your doctor.

If you forget to use it

If you forget to use Advantan(R), use it as soon as you remember. Then go on as before.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

If you use too much or use it other than directed (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much or swallowed some of this medicine. Do this even if there are no signs of discomfort or poisoning.

If you use too much Advantan(R) or use it for a long time, you may notice the following in the treated area:

- * your skin becomes thinner
- * pink/purple stretch marks appear
- * a network of tiny blood vessels appears.

Stop using Advantan(R) if you have these symptoms and tell your doctor.

These symptoms usually disappear about two weeks after you stop using Advantan(R).

While you are using Advantan(R)

Things you must do

Stop using Advantan(R) if you develop a skin allergy.

Tell your doctor if your skin becomes very dry when you use Advantan(R) cream or lotion. Your doctor may prescribe Advantan(R) ointment or fatty ointment instead.

If your eczema or psoriasis is infected, you must

- * use specific anti-infection treatments prescribed by your doctor
- * Stop using Advantan(R) if the infection spreads.

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Advantan(R).

If you become pregnant while using Advantan(R), tell your doctor immediately.

Things you must not do

Do not use Advantan(R) to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

See also the section with the heading Before you use Advantan(R).

Side effects

As with all medicines, Advantan(R) can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist:

- * if you have any unpleasant effects while you are using Advantan(R)

or

- * if you notice any of the following and they worry you:
 - itching
 - burning
 - redness.

The above list includes the more common side effects.

The following list includes side effects that are rare:

- thinning of the skin
- the appearance of fine blood vessels on the skin surface
- stretch marks
- acne
- infection of hair follicles

- excessive unwanted hair growth
- redness and irritation around the mouth (perioral dermatitis)
- skin discolouration
- allergic skin reactions.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Advantan(R)

Keep Advantan(R) in its pack until required.

Storage

Keep your Advantan(R) ointment or cream in a cool dry place where the temperature stays below 25 degrees C.

Keep your Advantan(R) fatty ointment or lotion in a cool dry place where the temperature stays below 30 degrees C.

Do not store Advantan(R) or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Advantan(R) where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use Advantan(R) after the expiry date on the pack.

Disposal

If your doctor tells you to stop using Advantan(R) or the expiry date has passed, ask your pharmacist what to do with any Advantan(R) that is left over.

Product description

What Advantan(R) formulations look like

Advantan(R) ointment is a white to yellowish, opaque ointment, with a firm consistency.

Advantan(R) fatty ointment is a white to yellowish, semi-clear ointment, which is greasier than Advantan(R) ointment.

Advantan(R) cream is a white cream, lighter in consistency than the ointments, and less greasy.

Advantan(R) lotion is a white lotion, more fluid than the cream.

Ingredients

Advantan(R) ointment contains 1 mg of methylprednisolone aceponate per gram of ointment as the active ingredient. It also contains

- * white beeswax
- * heavy liquid paraffin
- * white soft paraffin
- * Dehymuls E
- * water.

Advantan(R) fatty ointment contains 1 mg of methylprednisolone aceponate per gram of fatty ointment as the active ingredient. It also contains

- * heavy liquid paraffin
- * white soft paraffin
- * microcrystalline wax
- * hydrogenated castor oil.

Advantan(R) cream contains 1 mg of methylprednisolone aceponate per gram of cream as the active ingredient. It also contains

- * decyl oleate
- * glyceryl monostearate
- * cetostearyl alcohol
- * hard fat
- * Softisan 378
- * PEG-40 stearate
- * glyceryl 85%
- * butylated hydroxytoluene
- * benzyl alcohol

- * disodium edetate
- * water.

Advantan(R) lotion contains 1 mg of methylprednisolone aceponate per gram of lotion as the active ingredient. It also contains

- * medium chain triglycerides
- * caprylic/capric/stearic triglycerides
- * steareth-2
- * steareth-21
- * benzyl alcohol
- * disodium edetate
- * glycerol
- * water.

Advantan(R) does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

The Australian Registration Numbers are

Advantan(R) ointment AUST R 49381

Advantan(R) fatty ointment: AUST R 49382

Advantan(R) cream: AUST R 49380

Advantan(R) lotion: AUST R 80272

This is not all the information available on Advantan(R). If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Sponsor

Advantan(R) is sponsored in Australia by:

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