

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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# ADVANTAN

1 mg/g, ointment

METHYLPREDNISOLONE ACEPONATE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### What is in this leaflet?

1. What Advantan is and what it is used for
2. Before you take Advantan
3. How to take Advantan
4. Possible side effects
5. How to store Advantan
6. Further information

#### 1. WHAT ADVANTAN IS AND WHAT IT IS USED FOR

Advantan is anti-inflammatory medicine (corticosteroid) that is applied to the skin. Advantan stops the inflammatory and allergic reactions of the skin and therefore it relieves the symptoms that are caused by skin problems, such as redness (erythema), thickening of the skin, roughness of the skin surface, accumulation of fluids (edema), itching, and other problems (burning or pain).

#### **WHY TO USE ADVANTAN? (Indications)**

Advantan is used for the treatment of atopic dermatitis (endogenous eczema, neurodermatitis), eczema in children, contact eczema, degenerative, anhidrotic or vulgar eczema. Advantan is available in two different forms: in the form of cream and ointment, that are highly important for the therapeutic effect.

Advantan ointment is applied in certain skin diseases when skin is neither very dry or wet (i.e. it does not produce fluid), and the treatment requires a substrate with a balanced ratio of ointment and water. Advantan ointment makes the skin moderately oily without retention of heat and liquids. ADVANTAN ointment, when compared to other existing Advantan preparations, has the broadest field of application.

## 2. BEFORE YOU TAKE ADVANTAN

### **Do not take Advantan:**

- If you are hypersensitive (allergic) to methylprednisolone aceponate, or to any of the ingredients of Advantan.
- If you have a TB (tuberculosis) or syphilis at the application site, viral diseases (for example, chickenpox, herpes zoster), rosacea, perioral dermatitis or post-vaccination skin reactions on the area that is being treated.

### **Take special care with Advantan:**

If the doctor diagnosed that the skin disease is accompanied by bacterial or fungal infections, additional specific therapy should be considered.

If skin dries out significantly when applying Advantan, a formulation with a higher fat content, or Advantan ointment should be applied.

If you apply Advantan on your face, Advantan must not come into contact with the eyes.

Tell your doctor if you have a history of glaucoma. As it is generally known, development of glaucoma is possible with application of systemic corticosteroids (for example, after a significant or high dosage use over a prolonged period of time, occlusive method of treatment, or application to the skin around the eyes).

Application of topical steroids on a large area of the body or prolonged use, especially in occlusive treatment, significantly increase the risk of side effects.

Damage to the adrenal glands function were not reported in adults and children when applying the ointment to larger surface of the body (40-60% of the surface of the skin) or even in the case of occlusive treatment with Advantan. However, when applying to large areas of the body, the duration of use should be as short as possible.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

### **Pregnancy and breastfeeding**

#### **Pregnancy**

If you are pregnant, a doctor will take that into account before prescribing Advantan. Please, be sure to mention that you are pregnant, or that there is a possibility of pregnancy. As a general rule, the local preparations containing corticosteroids should not be used during the first trimester of pregnancy. In particular, avoid prolonged use on the large surface of the body.

#### **Breast feeding**

If you are breast-feeding a child, you should not apply Advantan on your breasts. A doctor will take into consideration that you are breast-feeding before prescribing Advantan, so please mention it. In particular, avoid prolonged application or application to large areas of the body.

### **Driving and using machines**

There are no known effects.

## 3. HOW TO TAKE ADVANTAN

A doctor will decide which preparation of Advantan (cream or ointment) is most suitable for you. Unless otherwise instructed, you should apply Advantan ointment in a thin layer once a day on the affected areas of skin. In general, the duration of treatment should not be longer than 12 weeks in adults and 4 weeks in children. If you think that Advantan's effect is too strong or too weak, talk to your doctor.

***If you take more Advantan than you should***

Do not worry. No risks are expected from a one-time overdose (that is, from a single application on a large surface of the body) or from accidental swallowing.

***If you forget to take Advantan***

Do not use increased amount of Advantan to make up for the dose that you missed.

***If you stop taking Advantan***

Please consult a doctor if first symptoms of skin disease reoccur.

If you have any further questions about the application of Advantan, talk to your doctor or pharmacist.

#### ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, Advantan may cause side effects.

In individual cases, the treatment with ADVANTAN may cause symptoms like itching, burning, redness (erythema) or blisters (vesiculation) in the area of diseased skin.

These reactions can occur when the local preparations containing corticosteroids are applied to large areas of the body (approximately 10% and more), or during a prolonged period of time (more than 4 weeks): symptoms, such as reduction of the skin (atrophy), telangiectasia, stretch marks, appearance of acne on the skin and systemic corticosteroid effects due to absorption. During the clinical trial none of these side effects occurred during treatment with Advantan up to twelve weeks (in adults) and up to four weeks (in children). As with other corticosteroids for local use, the side effects which may occur in rare cases are: inflammation of the hair follicle (folliculitis), increased hair growth (hypertrichosis), perioral dermatitis, skin discoloration, skin allergic reactions to any of the ingredients of the preparation.

If you notice any side effect, talk to your doctor or pharmacist.

#### ***5. HOW TO STORE ADVANTAN***

Keep out of reach and sight of children.

Store the medicine at a temperature below 25° C, protected from light.

Shelf life: 3 years

Advantan ointment must not be used after the expiry date stated on the packaging.

#### ***6. FURTHER INFORMATION***

***What does Advantan contain?***

Active substance of Advantan ointment is methylprednisolone aceponate.

1 g of Advantan ointment contains 1 mg of methylprednisolone aceponate.

***The other ingredients:***

white wax

liquid paraffin

dehymuls E (mixed pentaerythritol ester, fatty alcohol, fatty acid, and citric acid)

white Vaseline

Purified water

***Pharmaceutical form:***

Ointment

***Pharmacotherapeutic group:***

corticosteroid dermatic

What Advantan looks like and contents of the pack

White to slightly yellow ointment. Tube with 15 g of ointment in a box.

***Regime of dispensing***

The medicine is issued on prescription.

***Manufacturer***

Bayer Schering Pharma AG 13342 Berlin, Germany

***Manufacturer of the medicinal product***

Intendis Manufacturing S.P.A. Via e. Schering 21, Milan, Italy