

Package leaflet: information for the user
Aldara 5% cream
Imiquimod

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it is prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Aldara cream and what is it used for?
2. When should you not use this medicine or be extra careful with it?
3. How to use this medicine?
4. Possible side effects.
5. How to store this medicine?
6. Contents of the pack and other information

1. What is Aldara cream and what is it used for?

Aldara cream can be used for three different conditions. Your doctor may prescribe Aldara cream for the treatment of:

● Warts (condylomata acuminata) located on the outside of the genitalia and around the anus (between the buttocks).

● For superficial basal cell carcinoma.

This is a common and slow-growing form of skin cancer that is particularly unlikely to spread to other parts of the body. Generally, this condition occurs in middle-aged and older people, especially in patients with fair skin. The disease is caused by excessive sun exposure. If basal cell carcinoma is left untreated, it can cause disfigurement, particularly on the face. For this reason, it is important that the condition is detected and treated early.

● Actinic keratosis

Actinic keratoses are rough patches on the skin that have been excessively exposed to the sun during the patient's lifetime. The patches can be skin-colored, but gray, pink, red, or brown can also occur. The patches can be rough, scaly, hard, wart-like, flat, or lying on the skin. Aldara can only be used on flat actinic keratoses on the face or scalp. The patient must have a healthy immune system, and the doctor must have determined that Aldara is the most suitable treatment for you.

Aldara cream helps your body's immune system to produce natural substances that help fight your basal cell carcinoma, actinic keratosis, or the virus that caused your warts.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- o If you have previously used Aldara cream or other similar treatments, you must inform your doctor before starting this treatment.
- o If you have an immune disorder.
- o If you have had an organ transplant.
- o Use Aldara cream only after the area to be treated has healed from a previous treatment with medicines or a surgical procedure.
- o Avoid contact with the eyes, lips, and nostrils. In case of accidental contact, remove the cream by rinsing with water.
- o Do not apply the cream internally.
- o Do not use more cream than your doctor has recommended.
- o Do not cover the treated area with plasters or other dressings after applying Aldara cream.
- o If the treated area causes you too much discomfort, you should wash off the cream with mild soap and water. Once the skin reactions have disappeared, you can resume the treatment.
- o Inform your doctor if you have abnormal blood test results.

Due to the mechanism of action of Aldara, there is a chance that the cream may worsen an existing inflammation in the treated area.

- If you are being treated for genital warts, take these additional precautions:
 - Men who wish to treat warts under the foreskin should retract the foreskin daily and wash this area of skin. If the foreskin is not washed daily, there is a risk of narrowing, swelling, or thinning of the foreskin, or it becomes increasingly difficult to retract the foreskin. If one or more of these symptoms occur, you should stop the treatment immediately and consult your doctor.
 - If you have open sores: Do not use Aldara cream on areas of the skin where open sores are present until these sores have healed.
 - If you have internal warts: Do not use Aldara cream in the urethra (the urinary tract), the vagina (the birth canal), the cervix (internal female genital organ), or anywhere in the anus.

If you have severe problems with your immune system due to a disease or the medications you are using, you may only undergo one treatment with Aldara cream. If you think this applies to you, consult your doctor. If you are HIV-positive, you must inform your doctor as it has been shown that Aldara cream is less effective in these patients. If you decide to have sexual relations while you still have warts, apply the Aldara cream after sexual activity - not before.

Aldara cream can affect condoms and diaphragms, therefore the cream should not remain during sexual activity. Remember that Aldara cream does not protect against the possible transmission of HIV or other sexually transmitted infections to someone else.

- If you are being treated for basal cell carcinoma or actinic keratosis, take these additional precautions:

Do not use a sunlamp or tanning bed and avoid sunlight as much as possible during treatment with Aldara cream. Wear protective clothing and a wide-brimmed hat when outdoors. During the use of Aldara cream and until healing has occurred, the treated area will look noticeably different from normal skin.

Children and adolescents up to 18 years

Use by children and adolescents is not recommended.

Are you using any other medicines?

Are you using any other medicines besides Aldara cream, have you recently done so, or is there a possibility that you will use other medicines soon? Then tell your doctor or pharmacist.

There are no known medicines that are incompatible with Aldara cream.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Your doctor will discuss the risks and benefits of using Aldara cream during pregnancy with you. The results of animal studies do not indicate a direct or indirect harmful effect during pregnancy.

Do not breastfeed while using Aldara cream, as it is not known whether imiquimod is excreted in breast milk.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Aldara cream contains methylhydroxybenzoate, propylhydroxybenzoate (E216), cetyl alcohol, stearyl alcohol, and benzyl alcohol. Methylhydroxybenzoate (E 218) and propylhydroxybenzoate (E 216) may cause allergic reactions (possibly delayed). Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g., dermatitis).

This product contains 5 mg of benzyl alcohol in each sachet. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use this medicine?

Children and adolescents up to 18 years:

Use by children and adolescents is not recommended.

Adults:

Always use this medicine exactly as your doctor or pharmacist has told you.

Are you unsure about the correct use? Then contact your doctor or pharmacist.

Wash your hands carefully before and after applying the cream. Do not cover the treated area with bandages or other dressings after applying Aldara cream.

Use a new sachet each time you apply the cream. Discard any leftover cream after application. Do not save the opened sachet for another day. The treatment frequency and duration for genital warts, basal cell carcinoma, and actinic keratosis differ from each other (see the specific instructions for each indication).

Instructions for applying Aldara cream

● When being treated for genital warts:

Instructions for application – (Mon, Wed, and Fri)

1. Before going to bed, wash your hands and the area to be treated with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip
3. Rub a thin layer of Aldara cream onto the clean dry warts and gently rub until the cream is absorbed into the wart.
4. Discard the opened sachet after applying the cream and wash your hands with water and soap.
5. Leave the Aldara cream on the warts for 6 to 10 hours. Do not take a bath or shower during this time.
6. After 6 to 10 hours, the skin where the cream was applied should be washed with mild soap and water. cleaned.

Apply Aldara cream three times a week. For example, apply cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover an area of skin with warts the size of 20 cm². to cover.

Men with warts under the foreskin should retract it daily and wash the entire area (see section 2 “When should you be extra careful with this medicine?”)

Continue using Aldara cream until your warts have completely disappeared (in half of the women all warts will have disappeared in 8 weeks, in half of the men in 12 weeks, in certain patients, the warts may have disappeared after 4 weeks).

Do not use Aldara cream for more than 16 weeks for each (new) treatment of warts. If you feel that the effect of Aldara cream is too strong or too weak, discuss this with your doctor or pharmacist.

● When you are being treated for basal cell carcinoma:

Instructions for use – (Mon, Tue, Wed, Thu, and Fri)

1. Before going to bed, wash your hands and the area to be treated with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Rub a thin layer of Aldara cream on the affected area and 1 cm around it. Rub gently until the cream is absorbed into the skin.
4. Discard the opened sachet after applying the cream and wash your hands with water and soap.
5. Leave the Aldara cream on the skin for about 8 hours. Do not take a bath or shower during this time.
6. After 8 hours, wash the skin where the cream was applied with mild soap and water.

Apply enough Aldara cream daily for five consecutive days each week for six weeks to cover the treatment area and 1 centimeter around the treatment area. For example, apply the cream from Monday to Friday. On Saturday and Sunday, do not apply any cream. ● When being treated for actinic keratosis:

Instructions for use – (Mon, Wed, Fri)

Before going to bed, wash your hands and the treatment area with mild soap and water.

1. Dry thoroughly. Open a new sachet and squeeze some cream onto your fingertip.
2. Rub a thin layer of Aldara cream on the affected area. Rub gently until the cream is absorbed into the skin.
3. Discard the opened sachet after applying the cream and wash your hands with water and soap.
4. Leave the Aldara cream on the skin for about 8 hours. Do not take a bath or shower during this time.
5. Leave the Aldara cream on the skin for about 8 hours. Do not bathe during this time or shower.
6. Wash the skin where the cream was applied after 8 hours with mild soap and water.

Apply Aldara cream three times a week. For example, apply the cream on Monday, Wednesday and Friday. One sachet is sufficient to cover a skin area of 25 cm². Continue to use the cream for four weeks. Four weeks after the end of this first treatment, your doctor will assess your skin. If not all lesions have disappeared, another four weeks of treatment may be necessary.

Have you used too much of this medicine?

Rinse off the excess cream with mild soap and water. Once the skin reaction has disappeared, you can resume the treatment.

If you accidentally swallow Aldara cream, you should contact your doctor immediately.

Have you forgotten to use this medicine?

If you miss a dose, you should apply it as soon as you remember, then continue with your normal schedule.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

The frequency of side effects is classified as follows:

Very common side effects (likely to occur in more than 1 in 10 patients)

Common side effects (likely to occur in less than 1 in 10 patients)

Uncommon side effects (likely to occur in less than 1 in 100 patients)

Rare side effects (likely to occur in less than 1 in 1000 patients)

Very rare side effects (likely to occur in less than 1 in 10,000 patients).

Like any medicine, this medicine can have side effects, although not everyone experiences them. Inform your doctor or pharmacist as soon as possible if you feel unwell during a period when you are using Aldara cream.

Some patients experienced changes in skin color in the area where Aldara cream was applied. Although these changes usually diminish over time, reduce, or stop the use of Aldara cream, you should stop the treatment, wash the treated area with mild soap and water, and contact your doctor or pharmacist. A slight decrease in blood platelets has been observed in some patients. A decrease in

blood platelets can make you more susceptible to infections or bruise more easily. Fatigue may also occur. Tell your doctor if these symptoms occur. In some patients with an immune disorder, their condition may worsen. Do you have an immune disorder

and are using Aldara cream? Inform your doctor if there are any changes. Serious skin reactions have been rarely reported. If you find small wounds on your skin or small red spots that further develop, possibly with symptoms such as itching, fever, flu-like small spots that develop further, possibly with symptoms such as itching, fever, flu-like feeling, painful joints, vision problems, pain when swallowing, pain or itchy eyes or sores in the mouth, contact your doctor immediately.

A small number of patients experience hair loss on or around the treatment area.

● When you are being treated for genital warts:

Many of the unwanted side effects of Aldara cream are caused by the local action on your skin.

Very common side effects are redness (61% of patients), thinning of the skin (30% of patients), scaling and swelling. Hardening under the skin, small open sores, crusts like those that occur during normal wound healing, and small blisters under the skin may occur. After applying Aldara cream, you may experience itching (32% of patients), a burning sensation (26% of patients), or pain (8% of patients) in areas where you have applied the cream. Most of these skin reactions are mild in nature and the skin will recover approximately two weeks after discontinuation of treatment.

Often some patients (4% or less) have headaches, sometimes fever and flu-like symptoms, joint and muscle pain, uterine prolapse; in women, pain during intercourse; erectile dysfunction; increased sweating; nausea; stomach and intestinal complaints; ringing in the ears; flushing; fatigue; dizziness; migraine; numb limbs; insomnia; depression; decreased appetite; swollen glands; bacterial, viral, and fungal infections (e.g., sores); vaginal infection with white discharge; coughing and cold with sore throat reported.

Very rarely, serious and painful reactions have occurred, especially when more cream was applied than recommended. In very rare cases, it was difficult for women to urinate due to painful skin reactions at the vaginal opening. If this occurs, you should seek medical help immediately.

● When you are being treated for basal cell carcinoma:

Many of the side effects of Aldara cream are caused by the local action on the skin. Local skin reactions can be a sign that the medicine is working as intended.

A very common side effect is that the treated skin itches slightly.

Common side effects are numb limbs, small swellings in the skin, pain, burning sensation, irritation, bleeding, redness, or rash. If a skin reaction becomes too uncomfortable during treatment, talk to your doctor. He/she may advise you to stop using Aldara cream for a few days (i.e., to take a short break in the treatment). If there is pus or another symptom that indicates infection, discuss this with your doctor. In addition to skin reactions, other common side effects are swollen glands and back pain.

Sometimes some patients experience changes at the application site (discharge, inflammation, swelling, crusting, skin breakdown, blisters, dermatitis) or irritability, nausea, dry mouth, flu-like symptoms, and fatigue.

● When you are being treated for actinic keratosis:

Many of the side effects of Aldara cream are caused by the local action on the skin. Local skin reactions can be a sign that the medicine is working as intended.

A very common side effect is that the treated skin itches slightly.

Common side effects are pain, burning sensation, irritation, or redness.

If a skin reaction becomes too uncomfortable during treatment, talk to your doctor. He/she may advise you to stop using Aldara cream for a few days (i.e., to set a short break in the treatment). If there is pus or another symptom indicating infection, discuss this with your doctor. Besides skin reactions, other common side effects are headache, anorexia, nausea, muscle pain, joint pain, and fatigue.

Sometimes some patients experience changes at the application site (bleeding, inflammation, discharge, tenderness, swelling, small swollen areas of the skin, numb limbs, scaling, scarring, ulcers, or a feeling of warmth or discomfort) or inflammation of the inside of the nose, runny nose, flu or flu-like symptoms, depression, eye irritation, swollen eyelid, sore throat, diarrhea, actinic keratosis, redness, swollen face, ulcers, pain in limbs, fever, weakness, or chills.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly to help us obtain more information about the safety of this medicine. the national reporting system as mentioned in Appendix V. By reporting side effects, you can

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date. You can find it on the box and the label after "EXP". It includes a month and a year. The last day of that month is the expiry date. Once opened, sachets should not be reused. Do not flush medicines down the sink or toilet and do not throw them in the trash. Do not flush medications down the sink or toilet and do not throw them in the trash.

Ask your correctly, they will be destroyed responsibly and will not enter the environment. 6. Contents of the package and other information right.

The active substance in this medicine is imiquimod. Each sachet contains 250 mg cream (100 mg cream

What substances are in this medicine?

- The active substance in this medicine is imiquimod. Each sachet contains 250 mg cream (100 mg cream contains 5 mg imiquimod).
- The other ingredients in this medicine are isostearic acid, benzyl alcohol,
- cetyl alcohol, stearyl alcohol, soft white paraffin, polysorbate 60, sorbitan stearate, glycerol, nmethylparaben (E218), propylparaben (E216), xanthan gum, purified water. (See also section 2 "Aldara cream contains methylparaben,
- propylparaben (E216), cetyl alcohol, and stearyl alcohol and benzyl alcohol")

What does Aldara cream look like and what is in a package?

- Each sachet of Aldara cream 5% contains 250 mg of a white to pale yellow cream.
- Each box contains 12 or 24 polyester/aluminum foil sachets for single use. It may be that not all pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Viatrix Healthcare Limited
Damastown Industrial Park
Mulhuddart
Dublin 15
DUBLIN
Ireland

Manufacturer

Swiss Caps GmbH
Grassingerstraße 9
83043 Bad Aibling
Germany

For all information regarding this medicine, contact the local representative of the marketing authorization holder:

Belgium/Belgique/Belgien

Viatrix
Tél/Tel: +32 2 658 61 00

Bulgaria
Mylan EOOD

Tel: +359 2 44 55 400

Luxembourg/Luxemburg
Viatrix
Tél/Tel: +32 2 658 61 00
(Belgique/Belgien)

Hungary
Viatrix Healthcare Kft.
1138 Budapest
Váci út 150
Tel: +36 1 465 2100

Czech Republic
Viatrix CZ s.r.o.
Tel: +420 222 004 400

Malta
V.J. Salomone Pharma Limited
Tel: +356 21 22 01 74

Denmark
Viatrix ApS
Tel: +45 28 11 69 32

Germany
Viatrix Healthcare GmbH
Tel: +49 800 0700 800

Netherlands
Mylan Healthcare B.V.
Krijgsman 20
1186 DM Amstelveen
Tel: +31 (0)20 426 3300

Norway
Viatrix AS
Hagaløkkveien 26
1383 Asker
33

Estonia
Viatrix OÜ
Tel: +372 63 63 052

Greece
Viatrix Hellas Ltd
Tel: +30 210 010 0002

Spain
Viatrix Pharmaceuticals, S.L.
C/Plom, 2-4, 5th floor
08038 - Barcelona
Tel: +34 900 102 712

France
Viatrix Santé
1 bis place de la Défense – Tour Trinity
92400 Courbevoie
Tel: +33 (0)1 40 80 15 55

Croatia
Viatrix Croatia Ltd.
Koranska 2
10 000 Zagreb
Tel: +385 1 235 059 90

Ireland
Viatrix Limited
Tel: +353 1 8711600
Iceland
Icepharma hf
Tel: +354 540 8000

Italy
Viatrix Italy
Via Vittor Pisani,
2020124 Milan
Tel: +39 (0) 2 612 46921

Cyprus
CPO Pharmaceuticals Limited
Tel: +357 22863100

Latvia
Viatrix SIA
101 Mūkusalas str.
Rīga LV-1004
Tel: +371 67616137
Tel: +47 66 75 33 00

Austria
Viatrix Austria GmbH
Guglgasse 15
1110 Vienna

Tel: + 43 (0)1 86 390

Poland
Viatriis Healthcare Sp. z o.o.
ul. Postępu 21B
02-676 Warsaw
Tel: +48 22 546 6400

Portugal
Viatriis Healthcare, Lda.
Av. D. João II,
Edifício Atlantis, nº 44C – 7.3 e 7.4
1990-095 Lisbon
Tel: +351 214 127 200

Romania
BGP PRODUCTS SRL
Tel.: +40372 579 000

Slovenia
Viatriis d.o.o.

Tel: +386 1 23 63 180

Slovak Republic
Viatriis Slovakia s.r.o.
Tel: +421 2 32 199 100
Finland
Viatriis Oy
Puh/Tel: +358 20 720 9555

Sweden
Viatriis AB
Box 23033
104 35 Stockholm
+46 (0) 8 630 19 00

Lithuania
Viatriis UAB
Žalgirio str. 90-100
Vilnius LT-09303
Tel. + 370 52051288

This leaflet was last approved in
More information about this medicine is available on the website of the European
Medicines Agency (<http://www.ema.europa.eu>).