

Patient Information
ALDARA [al dar' a] Cream, 5%
(Imiquimod)

IMPORTANT: Not for mouth, eye, or vaginal use

Read the Patient Information that comes with Aldara Cream before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment. If you do not understand the information, or have any questions about Aldara Cream, talk with your healthcare provider or pharmacist.

What is Aldara Cream?

Aldara Cream is a skin use only (topical) medicine used to treat:

- external genital and perianal warts in people 12 years and older
- actinic keratosis in adults with normal immune systems. Actinic keratosis is caused by too much sun exposure.
- superficial basal cell carcinoma in adults with normal immune systems when surgical methods are less appropriate. This skin cancer needs to be diagnosed by your healthcare provider.

Aldara Cream is used in different ways for the three different skin conditions it is used to treat. It is very important that you follow the instructions for your skin condition. Talk to your healthcare provider if you have questions.

Aldara Cream does not work for everyone. Aldara Cream will not cure your genital or perianal warts. New warts may develop during treatment with Aldara Cream. It is not known if Aldara Cream can stop you from spreading genital or perianal warts to other people. For your own health and the health of others, it is important to practice safer sex. Talk to your healthcare provider about safer sex practices.

Who should not use Aldara Cream?

- Aldara Cream has not been studied in children under 12 years old for external genital and perianal warts.
- Aldara Cream has not been studied in children under 18 years old for actinic keratosis or superficial basal cell carcinoma. Children usually do not get actinic keratoses or basal cell carcinoma.

Before using Aldara Cream, tell your healthcare provider:

- **about all your medical conditions, including if you**
 - **are pregnant or planning to become pregnant.** It is not known if Aldara Cream can harm your unborn baby.
 - **are breastfeeding.** It is not known if Aldara Cream passes into your milk and if it can harm your baby.

- **about all the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements.** Especially tell your healthcare provider if you have had other treatments for genital or perianal warts, or actinic keratosis, or superficial basal cell carcinoma. Aldara Cream should not be used until your skin has healed from other treatments.

How should I use Aldara Cream?

- Use Aldara Cream exactly as prescribed by your healthcare provider. **Aldara Cream is for skin use only. Do not take by mouth or use in or near your eyes, lips or nostrils.** Do not use Aldara Cream unless your healthcare provider has taught you the right way to use it. Talk to your healthcare provider if you have any questions.
- Aldara Cream is used for several skin conditions. **Use Aldara cream only on the area of your body to be treated.** Your healthcare provider will tell you where to apply Aldara cream and how often and for how long to apply it for your condition. Do not use Aldara Cream longer than prescribed. Using too much Aldara Cream, or using it too often, or for too long can increase your chances for having a severe skin reaction or other side effect. Talk to your healthcare provider if Aldara Cream does not work for you.

For external genital and perianal warts Aldara Cream is usually used once a day for 3 days a week:

- Monday, Wednesday and Friday, or
- Tuesday, Thursday and Saturday

For these conditions, Aldara Cream is usually left on the skin for 6 to 10 hours. Treatment should continue until the warts are completely gone, or up to 16 weeks.

For actinic keratosis Aldara Cream is usually used once a day for 2 days a week, 3 to 4 days apart, such as:

- Monday and Thursday, or
- Tuesday and Friday

For this condition, Aldara Cream is usually left on the skin for about 8 hours. Treatment should continue for the full 16 weeks even if all actinic keratoses appear to be gone, unless you are told otherwise by your healthcare provider. The area you treat with Aldara Cream should be no larger than approximately the size of your forehead or one cheek (for example 2 inches by 2 inches), unless otherwise directed by your healthcare provider.

For superficial basal cell carcinoma Aldara Cream is usually used once a day for 5 days a week:

- Monday, Tuesday, Wednesday, Thursday and Friday

For this condition, Aldara Cream is usually left on the skin for about 8 hours. Your healthcare provider will show you how much Aldara Cream to apply to your superficial basal cell carcinoma. You should also apply Aldara Cream to a small area of skin all around the superficial basal cell carcinoma. This small area of skin should be about the size of your

fingertip. Treatment should continue for the full 6 weeks, even if the superficial basal cell carcinoma appears to be gone, unless you are told otherwise by your healthcare provider.

Applying Aldara Cream

Aldara Cream should be applied just before your bedtime.

- Wash the area to be treated with mild soap and water. Allow the area to dry.
 - Uncircumcised males treating warts under their penis foreskin must pull their foreskin back and clean before treatment, and clean daily during the weeks of treatment.
- Wash your hands
- Open a new packet of Aldara Cream just before use
- Apply a thin layer of Aldara Cream **only** to the affected area or areas to be treated. Do not use more Aldara cream than is needed to cover the treatment area.
- Rub the cream in all the way to the affected area or areas.
 - Do not get Aldara Cream in your eyes.
 - Do not get Aldara Cream in the anus when applying to perianal warts.
 - Female patients treating genital warts must be careful when applying Aldara Cream around the vaginal opening. Female patients should take special care if applying the cream at the opening of the vagina because local skin reactions on the delicate moist surfaces can cause pain or swelling, and may cause problems passing urine. Do not put Aldara Cream in your vagina or on the skin around the genital wart.
- Do not cover the treated area with an airtight bandage. Cotton gauze dressings can be used. Cotton underwear can be worn after applying Aldara Cream to the genital or perianal area.
- Safely throw away the open packet of Aldara Cream so that children and pets cannot get it. The open packet should be thrown away even if all the Aldara Cream was not completely used.
- After applying Aldara Cream, **wash your hands well**.
- Leave the cream on the affected area or areas for the time prescribed by your healthcare provider. The length of time that Aldara Cream is left on the skin is not the same for the different skin conditions that Aldara Cream is used to treat. Do not bathe or get the treated area wet before the right time has passed. Do not leave Aldara Cream on your skin longer than prescribed.
- After the right amount of time has passed, wash the treated area or areas with mild soap and water.
- If you forget to apply Aldara Cream, apply the missed dose of cream as soon as you remember and then continue on your regular schedule.
- If you get Aldara Cream in your mouth or in your eyes rinse well with water right away.

What should I avoid while using Aldara Cream?

- Do not cover the treated site with bandages or other closed dressings. Cotton gauze dressings are okay to use, if needed. Cotton underwear can be worn after treating the genital or perianal area.
- Do not apply Aldara Cream in or near the eyes, lips or nostrils, or in the vagina or anus.

- Do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Aldara Cream. Use sunscreen and wear protective clothing if you go outside during daylight.
- Do not have sexual contact including genital, anal, or oral sex when Aldara Cream is on your genital or perianal skin. Aldara Cream may weaken condoms and vaginal diaphragms. This means they may not work as well to prevent pregnancy. For your own health and the health of others, it is important to practice safer sex. Talk to your healthcare provider about safer sex practices.

What are the possible side effects of Aldara Cream?

The most common side effects with Aldara Cream are skin reactions at the treatment site including:

- redness
- swelling
- a sore, blister, or ulcer
- skin that becomes hard or thickened
- skin peeling
- scabbing and crusting
- itching
- burning
- changes in skin color that do not always go away

Actinic Keratosis

During treatment and until the skin has healed, your skin in the treatment area is likely to appear noticeably different from normal skin. Side effects, such as redness, scabbing, itching and burning are common at the site where Aldara Cream is applied, and sometimes the side effects go outside of the area where Aldara Cream was applied. Swelling, small open sores and drainage may also be experienced with use of Aldara Cream. You may also experience itching and/or burning. Actinic keratoses that were not seen before may appear during treatment and may later go away. If you have questions regarding treatment or skin reactions, please talk with your healthcare provider.

Superficial Basal Cell Carcinoma

During treatment and until the skin has healed, your skin in the treatment area is likely to appear noticeably different from normal skin. Side effects, such as redness, swelling and a sore are common at the site where Aldara Cream is applied. You may also experience itching or burning. Your healthcare provider will need to check the area that was treated after your treatment is finished to make sure that the skin cancer is gone. Superficial basal cell carcinoma can come back. The chances of it coming back are higher as time passes. **It is very important to have regular follow-up visits with your healthcare provider to check the area to make sure your skin cancer has not come back. Ask your healthcare provider how often you should have your skin checked.** Talk with your healthcare provider if you have questions about your treatment or skin reactions.

External Genital and Perianal Warts

Patients should be aware that new warts may develop during treatment, as Aldara Cream is not a cure. Many people see reddening or swelling on or around the application site during the course of treatment. If you have questions regarding treatment or local skin reactions, please talk with your healthcare provider.

You have a higher chance for severe skin reactions if you use too much Aldara Cream or use it the wrong way. **Stop Aldara Cream right away and call your healthcare provider if you get any skin reactions that affect your daily activities, or that do not go away.** Sometimes, Aldara Cream must be stopped for a while to allow your skin to heal. Talk to your healthcare provider if you have questions about your treatment or skin reactions.

Other side effects of Aldara Cream include headache, back pain, muscle aches, tiredness, flu-like symptoms, swollen lymph nodes, diarrhea, and fungal infections.

If the reactions seem excessive, if either skin breaks down or sores develop during the first week of treatment, if flu-like symptoms develop or if you begin to not feel well at anytime, contact your healthcare provider.

These are not all the side effects of Aldara Cream. For more information, ask your healthcare provider or pharmacist.

How do I store Aldara Cream?

- **Store Aldara Cream at 39 - 77° F (4 - 25° C).** Do not freeze.
- Safely throw away Aldara Cream that is out of date or that you do not need.
- **Keep Aldara Cream and all medicines out of the reach of children.**

General information about Aldara Cream

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Aldara Cream for a condition for which it was not prescribed. Do not give Aldara Cream to other people, even if they have the same symptoms you have.

This leaflet summarizes the most important information about Aldara Cream. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Aldara Cream that is written for the healthcare provider. If you have other questions about Aldara Cream, call 1-888-2-ALDARA.

What are the ingredients in Aldara Cream?

Active Ingredient: imiquimod

Inactive ingredients: isostearic acid, cetyl alcohol, stearyl alcohol, white petrolatum, polysorbate 60, sorbitan monostearate, glycerin, xanthan gum, purified water, benzyl alcohol, methylparaben, and propylparaben.

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