Summary of patient information for external genital and perianal warts
About Aldara™
(IMITQUIMOD) Cream

PLEASE READ THIS BEFORE USING ALDARA CREAM TO TREAT EXTERNAL GENITAL AND PERIANAL WARTS (HUMAN PAPILLOMAVIRUS [HPV] INFECTION).

3M Pharmaceuticals wants you to know about the medicine you use. However, this information does not replace advice given by your doctor or healthcare provider. If you have any questions about ALDARA cream, your healthcare provider can discuss them with you.

What is ALDARA cream?
ALDARA cream is used to treat external genital and perianal warts in people 12 years and older. Do not use it to treat internal warts.

How does ALDARA cream work?
ALDARA cream is an immune response modifier. The way in which it gets rid of genital warts is unknown.

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

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. No 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 wart.
  - 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, may cause problems passing urine. Do not put Aldara Cream in your vagina or on the skin around the genital wart.
• 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.

Can I have sex while using ALDARA cream?

Sexual contact should be avoided while the cream is on the skin. If you decide to have sexual relations, apply ALDARA cream after—not before—sexual activity. If you have already applied the cream, it should be washed off before sexual activity. In addition, ALDARA cream may weaken condoms and diaphragms; therefore the cream should not be left on during sexual activity. The effect of ALDARA cream on transmission of genital warts is unknown.

What if I forget a dose?

Apply the missed dose of cream as soon as you remember and then continue on the regular schedule.
What can I expect from ALDARA cream?

Results vary from person to person. Many people see reddening or swelling on or around the warts during the course of treatment.

In clinical trials, about one-half of patients completely got rid of their warts. In most patients, the warts disappeared in 8 to 12 weeks. However, some patients got rid of their warts in 4 weeks and others took up to 16 weeks. For best results with ALDARA cream, follow your healthcare provider’s instructions closely.
Will I get any side effects from 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
- changes in skin color that do not always go away
- skin peeling
- scabbing and crusting
- itching
- burning

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.

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 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.

**Who should not use ALDARA cream?**

ALDARA cream has not been studied in pregnant women. If you are pregnant, check with your healthcare provider to find out if he or she feels that ALDARA cream is clearly needed. Aldara Cream has not been studied in children under 12 years old for external genital and perianal warts.

**Is there anything else I should know about ALDARA cream?**

As with any prescription medicine, there are some general rules you should follow:

- Always use ALDARA cream as directed by your doctor or healthcare provider
- Try to stick to your dosing schedule
- Discard any unused cream after each application
- Do not share ALDARA cream with anyone else; it was prescribed only for you
- Keep ALDARA cream and all medicines out of the reach of children
BE INFORMED ABOUT GENITAL WARTS

What are genital and perianal warts?

Genital and perianal warts are growths or bumps that appear in or around the entrance of the vagina or anus, or on the vulva, cervix, penis, scrotum, groin, or thigh. They are caused by the human papillomavirus (HPV), which can be passed from person to person during sexual contact.

What everyone should know about genital warts

Genital warts may be raised or flat, single or multiple, small or large. They may cluster together to form a cauliflower-like shape. Often, they are flesh-colored and painless.

There are many types of HPV infections, some causing external warts and others causing potential infections in the cervix. It is important for women to see their healthcare providers regularly for pelvic exams and Pap smears. If your sex partner tells you that he or she has HPV or genital warts, it is important to see your healthcare provider. It is important for you, once your warts are gone, to get regular checkups at least once a year.

NOTE: This summary provides important information about ALDARA cream. For other important information, please see the product information available from your pharmacist. If you have medical questions, ask your healthcare professional.