

Summary of Patient Information  
About Aldara™ (Imiquimod) Cream, 5%

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. 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 do I use ALDARA cream?**

ALDARA cream is rubbed directly on the wart(s). It should not be taken by mouth or used in or near the eyes.

**To use ALDARA cream:**

1. Wash hands and open a new packet of Aldara cream just before bedtime
2. Apply a thin layer of cream on the wart(s)
3. Rub the cream in until it vanishes
4. Discard the open packet and wash hands
5. Leave the cream on the wart(s) for 6 to 10 hours
6. After 6 to 10 hours, wash the area where Aldara cream was applied with mild soap and water

Always apply ALDARA cream as directed by your healthcare provider.

**When should I use ALDARA cream?**

It is important to use ALDARA cream as directed by your healthcare provider.

Typically, dosing is once a day, 3 days a week:

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

Apply ALDARA cream at bedtime, after bathing, so you do not wash off the cream.

Treatment with ALDARA cream should continue until the warts are completely gone, or up to 16 weeks. Your healthcare provider can tell you how often and for how long you need to use ALDARA cream.

**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. Patients should be aware that new warts may develop during therapy, as Aldara cream is not a cure. For best results with ALDARA cream, follow your healthcare provider's instructions closely.

**Will I get any side effects from ALDARA cream?**

There are some side effects associated with ALDARA cream. Side effects are usually mild to moderate.

Most common side effects are redness, peeling, and swelling in the area where ALDARA cream is applied.

Some patients have also experienced burning and itching where ALDARA cream was applied. These may be caused by the response of your body's immune system to the drug. However, if you experience a severe reaction, contact your healthcare provider.

**What should I avoid while using ALDARA cream?**

Do not cover warts with bandages or other closed dressings. Avoid using overly large amounts of cream. A thin layer that completely covers each wart is enough.

**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. Additionally, ALDARA cream should not be applied to warts inside the vagina or anus.

**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

Reference: 1. Data on file (1004-IMI), 3M Pharmaceuticals.

**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 is generally 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.

If you have other questions about ALDARA cream, call 1-888-2-ALDARA.