

Aldara(TM) Cream 5%

Imiquimod

Consumer Medicine Information

What is in this Leaflet

This leaflet answers some common questions about Aldara. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. If you need any more information about Aldara, please ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using Aldara against the benefits it can have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine as you may want to read it again.

Your Medicine

The name of your medicine is Aldara. Aldara cream contains the active ingredient imiquimod. Imiquimod is an immune response modifier. It activates immune cells in the body. The immune cells then proceed to kill and remove the virus-infected or cancer cells. Although the exact way that Aldara works is unknown, it is believed to be due to its effects on the immune system.

What Aldara is used for

Aldara is used to treat solar keratosis (SK) on the face and scalp, superficial basal cell carcinoma (sBCC), and genital/perianal warts.

- * Solar keratoses are thickened, scaly patches of skin caused by too much sun exposure. Solar keratosis is also known as actinic keratosis.
- * Basal cell carcinoma is a type of skin cancer.
- * External genital/perianal warts (condyloma acuminata) are warts that appear on the surface of the penis or vulva (external female sexual organ) and around the anus.

Aldara is not recommended for use in patients under the age of 18 years as there have been no studies of its effects in this age group.

Your doctor may prescribe Aldara for another purpose. If you are not sure why you are using this medicine ask your doctor.

Before using Aldara

When you must not use Aldara

Do not use Aldara:

- * if you are allergic to imiquimod or to any of the ingredients listed under "Product Description"

- * on skin where there are open sores or wounds. Do not start using Aldara until after the area has healed.
- * on warts inside the vagina or inside the anus or inside the urethra (where you pass urine). The use of Aldara cream on these areas has not been studied.
- * on areas that are sunburnt
- * if the packaging is torn, or shows signs of tampering.
- * after the "use by" date shown on the box or sachet or after 4 weeks from first opening the Aldara pump.

Before you start to use Aldara

Tell your doctor if:

- * you are pregnant or intend to become pregnant.
- * you are breastfeeding or intend to breastfeed.
- * you are or you think you are HIV positive.
- * you are taking any other medicines
- * you have previously used Aldara cream or other similar preparations to treat your condition.
- * you have problems with your immune system
- * you have an abnormal blood count
- * you currently have, or in the past have had, any other medical conditions.

Using Aldara

Dosage

Aldara is used to treat several skin conditions. Your doctor will tell you where to apply Aldara cream, how often and for how long to apply it for your condition. Aldara should be applied just before bedtime and left on the skin for 6-10 hours. Sufficient cream should be applied to cover the treatment area. Talk to your doctor if your condition re-appears after treatment.

Solar Keratosis

If your doctor has prescribed Aldara for the treatment of SK, the usual dosage is once a day, at bedtime, three times a week. For three times a week application, Aldara can be applied, for example, on Monday, Wednesday and Friday, or Tuesday, Thursday and Saturday.

- * Your doctor may tell you to continue applying Aldara cream for 4 weeks, followed by a period of 4 weeks without any treatment. Your doctor will then check your skin condition. If any SK lesions remain, the treatment should be repeated for another four weeks.
- * Alternatively, your doctor may want you to continue applying Aldara cream for up to 16 weeks. Each treatment should continue for no more than 16 weeks at a time.

Superficial Basal Cell Carcinoma

If your doctor has prescribed Aldara for the treatment of sBCC, it should be applied to the affected area once a day at bedtime for five consecutive days per week (Monday to Friday), or as recommended by your doctor. Treatment should continue for 6 weeks unless your doctor tells you otherwise.

External Genital or Perianal Warts

If your doctor has prescribed Aldara for the treatment of external genital or perianal warts, it is to be applied

once a day, at bedtime, three times a week or as recommended by your doctor.

For three times a week application, Aldara can be applied on Monday, Wednesday and Friday; or Tuesday, Thursday and Saturday. Treatment should continue until the warts are completely gone. Aldara should not be used for more than 16 weeks at a time. It usually takes 8-10 weeks for your warts to disappear but warts may clear as early as 4 weeks. If your warts reappear, talk to your doctor.

If your skin reacts badly to Aldara, your doctor may recommend that you stop treatment for a few days. It is not necessary to make up the doses that you missed or to prolong the treatment period.

How to use Aldara

1. Before applying Aldara, wash your hands and treatment area with mild soap and water and allow it to dry thoroughly. If you are using Aldara pump remove the protective cap and prime several times until cream appears at the nozzle. Alternatively, open a sachet of Aldara and squeeze some cream onto your fingertip.
2. Apply a thin layer of Aldara cream onto the treatment area and rub it gently into the skin until the cream vanishes. For sBCC lesions enough cream should be applied to cover the lesion and about 1cm of surrounding skin. If using the pump, four actuations of the pump is equivalent to the content of one 250 mg sachet of Aldara cream. One sachet contains enough cream to cover a treatment area of 20 square centimetres (approximately 3 square inches).
3. If using the pump, replace the protective cap back on the pump after application of the cream. Carefully store where children cannot reach it. Wash your hands with mild soap and water. If using the sachet after application of the

cream, carefully dispose of the unused Aldara cream in the sachet where children cannot reach it.

Once opened, the contents of the pump are to be used within 4 weeks.

4. Leave Aldara cream on the affected area for 6 to 10 hours. Do not shower or bathe during this time.
5. After 6-10 hours, the area where Aldara cream was applied should be washed with mild soap and water.

While you are using Aldara

- * Do not use more than the recommended amount of Aldara cream. A thin layer that completely covers the treatment area and surrounding skin is enough.
- * Do not cover the treatment area with bandages or other dressings after you have applied Aldara cream. Cotton gauze dressings are okay to use, if needed.
- * Stop using Aldara cream if you become pregnant, and do not use it if you are breastfeeding.

If you are using Aldara to treat SK:

- * Aldara cream should not be applied in or near the eyes, lips or nostrils.
- * Do not use sunlamps or tanning beds, and avoid going into the sun as much as possible during treatment with Aldara cream. Wear protective clothing if you go outside during daylight.
- * New SK lesions may develop during treatment with Aldara cream. These lesions may resolve during the treatment period. Even though the initial SK lesions may clear with treatment, new lesions may develop in the future and require further treatment. Aldara cream is not a cure, since SK is considered to be a chronic skin condition.

- * There is not enough data to support the use of Aldara to treat SK on the hands and arms.
- * Aldara cream should not be applied to an area greater than 25 square centimetres.

If you are using Aldara to treat sBCC:

- * Aldara cream should not be applied in or near the hairline, eyes, ears, nose or lips.
- * Do not use sunlamps or tanning beds, and avoid going into the sun as much as possible during treatment with Aldara cream. Wear protective clothing if you go outside during daylight.
- * Visit your doctor regularly if you are treating more than one sBCC lesion at the same time.

If you are using Aldara to treat genital warts:

- * Avoid sexual (genital, anal or oral) contact. 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.
- * Aldara cream may weaken condoms and diaphragms; therefore, the cream should be washed off before using a condom or diaphragm during sexual activity. Alternate forms of contraception should be considered.
- * The effect of Aldara cream on the transmission of genital warts is not known.
- * Uncircumcised men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If daily washing under the foreskin is not carried out, tightness of the foreskin may occur. Early signs of tightness include swelling and wearing away of the skin, or difficulty in pulling back the foreskin. If these symptoms occur, stop the

treatment immediately and call your doctor.

- * Female patients should take special care if applying Aldara cream at the opening of the vagina because local skin reactions on the delicate moist surfaces can result in pain or swelling, and may cause difficulty in passing urine.
- * Do not use Aldara for more than one course if you have problems with your immune system either due to illness or because of the medicines you are already taking. If you think this applies to you, talk to your doctor.

Aldara cream has been prescribed for your use only. Do not give it to anyone else even if you think their condition is the same as yours.

If you forget to use Aldara

If you forget a dose, apply the missed dose of cream as soon as you remember and then continue on the regular schedule. Do not double the dose at any time to make up the missed dose.

Side Effects

All medicines can have side effects and this may occur with the normal use of Aldara. Tell your doctor as soon as possible if you do not feel well while you are using Aldara.

More Common Side Effects of Aldara

The following effects have occurred during clinical trials with Aldara cream. If the following occur and are severe enough to worry you, tell your doctor.

- * Application site reactions including redness, wearing away of the skin, flakiness, swelling, hardening under the skin, small open sores, crust that forms

during healing, small bubbles under the skin, itching, burning, pain, tenderness, irritation, rash, soreness, stinging, sensitivity, skin colour becomes lighter, bleeding, lumps on the skin, infection and pimples. Most of these skin reactions are mild to moderate, and are signs that the product is working. If your skin reacts badly or the skin reaction becomes too uncomfortable when using Aldara cream, wash the cream off with mild soap and water and contact your doctor. Your doctor may recommend that you stop treatment for a few days.

- * Flu symptoms, tiredness, fever, headache, diarrhoea, back pain, muscle pain, and swollen glands in the neck, armpit and groin.

Some patients have experienced changes in skin colour (lighter or darker) in the area where Aldara cream was applied. These changes may be permanent in some cases.

Please tell your doctor if you experience other side effects or you do not feel well while you are using Aldara.

If you use too much Aldara

Using too much Aldara cream could cause severe skin reactions. If too much cream is applied, simply wash away the extra cream with mild soap and water. When any skin reaction has settled, you may then continue with your treatment.

If the cream is accidentally swallowed, nausea, vomiting, headache, muscle pain, and fever could occur. If you or someone else accidentally swallows Aldara cream, contact your doctor or Poisons Information Centre (in Australia call 131126; in New Zealand call toll free 0800 POISON or 0800 764 766) or go to the Accident and Emergency department at the nearest hospital.

After Using Aldara Cream

Storage

Aldara cream should be kept in a cool dry place where the temperature stays below 25 degrees C. Do not freeze.

Discard Aldara pump 4 weeks after opening.

Do not store Aldara cream or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep Aldara pump and sachets of Aldara where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Aldara or it has past its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What Aldara cream looks like

Aldara cream is a white to slightly yellow cream, packed in a pump or single-use foil sachet. Four actuations of the pump is approximately equivalent to one sachet containing 250 mg of Aldara cream. In both cases this is enough cream to cover a treatment area of 20 square centimetres. In Australia Aldara cream is supplied in a pack containing one or two pumps and is also available in a wallet of 1 sachet and boxes of 6 and 12 sachets.

Ingredients

Each 250mg of Aldara cream 5% contains 12.5mg of the active ingredient, imiquimod. Aldara cream also contains isostearic acid, benzyl alcohol, cetyl alcohol, stearyl alcohol, white soft paraffin, polysorbate 60, sorbitan monostearate, glycerol, methyl hydroxybenzoate, propyl hydroxybenzoate, xanthan gum, purified water.

Sponsor

Aldara is distributed in Australia by:

iNova Pharmaceuticals (Australia) Pty. Limited.

(ABN 88 000 222 408)

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