

ALDIQ

imiquimod

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALDIQ. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ALDIQ against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ALDIQ is used for

ALDIQ is used to treat:

- Solar keratosis (SK) on the face and Superficial Basal Cell Carcinoma (sBCC)

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.

- Genital/perianal warts

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.

ALDIQ 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.

ALDIQ 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 ALDIQ works is unknown, it is believed to be due to its effects on the immune system.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before using it

When you must not use it

Do not use ALDIQ if you have an allergy to:

- any medicine containing imiquimod
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use ALDIQ:

- on skin where there are open sores or wounds. Do not start using ALDIQ 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 ALDIQ cream on these areas has not been studied.

- on areas that are sunburnt.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- if you are or you think you are HIV positive
- you have previously used ALDIQ cream or other similar preparations to treat your condition
- problems with your immune system
- currently have, or in the past have had, any other medical conditions
- have had any organ transplants
- have molluscum contagiosum (molluscum)

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking ALDIQ.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ALDIQ may interfere with each other. These include:

- immunosuppressive medicines used to suppress your immune system

These medicines may be affected by ALDIQ or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ALDIQ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to use

ALDIQ is used to treat several skin conditions. Your doctor will tell you where to apply ALDIQ cream, how often and for how long to apply it for your condition.

Solar Keratosis

If your doctor has prescribed ALDIQ for the treatment of SK, the usual dosage is once a day, at bedtime, three times a week. For three times a

week application, ALDIQ can be applied, for example, on Monday, Wednesday and Friday, or Tuesday, Thursday and Saturday.

- Your doctor may tell you to continue applying ALDIQ 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 ALDIQ 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 ALDIQ 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 ALDIQ 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, ALDIQ can be applied on Monday, Wednesday and Friday; or Tuesday, Thursday and Saturday. Treatment should continue until the warts are completely gone. ALDIQ 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 ALDIQ, 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 it

ALDIQ 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.

1. Before applying ALDIQ, wash your hands and treatment area with mild soap and water and allow it to dry thoroughly. Open a sachet of ALDIQ and squeeze some cream onto your fingertip.
2. Apply a thin layer of ALDIQ 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. One sachet contains enough cream to cover a treatment area of 20 square centimetres (approximately 3 square inches).
3. If using the sachet after application of the cream, carefully dispose of the unused ALDIQ cream in the sachet where children cannot reach it. Wash your hands with mild soap and water.
4. Leave ALDIQ 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 ALDIQ cream was applied should be washed with mild soap and water.

While you are using ALDIQ

- Do not use more than the recommended amount of ALDIQ 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 ALDIQ cream. Cotton gauze dressings are suitable to use, if needed.

If you are using ALDIQ to treat Solar Keratosis

- ALDIQ 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 ALDIQ cream. Wear protective clothing if you go outside during daylight.
- New SK lesions may develop during treatment with ALDIQ 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. ALDIQ cream is not a cure, since SK is considered to be a chronic skin condition.
- There are not enough data to support the use of ALDIQ to treat SK on the hands and arms.
- ALDIQ cream should not be applied to an area greater than 25 square centimetres.

If you are using ALDIQ to treat Superficial Basal Cell Carcinoma:

- ALDIQ 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 ALDIQ 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 ALDIQ to treat genital warts:

Genital warts are very contagious, therefore avoid sexual (genital, anal or oral) contact.

If you do decide to have sexual relations, apply ALDIQ cream after, not before, sexual activity. If you

have already applied the cream, it should be washed off before sexual activity.

ALDIQ 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 ALDIQ 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 ALDIQ 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 ALDIQ 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.

ALDIQ 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 it

Skip the application you missed and apply your next treatment when you are meant to.

Otherwise, apply it as soon as you remember, and then go back to applying your medicine as you would normally.

Do not apply a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to apply your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used or swallowed too much ALDIQ. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose from too much ALDIQ applied topically may result in severe skin reactions.

Symptoms of an overdose from swallowing ALDIQ orally include:

- nausea
- vomiting
- headache
- fever
- low blood pressure

While you are using ALDIQ

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ALDIQ.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not use ALDIQ to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ALDIQ.

This medicine helps most people with the previously mentioned illnesses, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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 ALDIQ 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 ALDIQ cream was applied. These changes may be permanent in some cases.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using ALDIQ

Storage

Keep your cream in a cool dry place where the temperature stays below 25°C.

Do not store ALDIQ or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ALDIQ cream is a white to slightly off white cream, packed in a single-use foil sachet. This is enough cream to cover a treatment area of 20 cm². In Australia ALDIQ cream is supplied in boxes of 6 and 12 sachets.

Ingredients

Each ALDIQ sachet contains 12.5 mg of imiquimod as the active ingredient.

The cream also contains the following inactive ingredients:

- benzyl alcohol
- cetyl alcohol
- glycerol
- isostearic acid
- methyl hydroxybenzoate
- polysorbate 60
- propyl hydroxybenzoate
- purified water
- sorbitan monostearate
- stearyl alcohol
- white soft paraffin
- xanthan gum

Distributor

ALDIQ is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

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