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Pharmaceutical  
Services by Novolog

<b>Product</b>	<b>Aldara 5%</b>	<b>Size</b>	350 x 355 mm
<b>Product spec</b>	<b>Solution</b>		(W) x (H)
		<b>Font (type &amp; min. size / language)</b>	Arial 7p (Heb, Arb, Eng)
	Aldara-Cream- Leaflet-05.indd		
<b>Tech ref</b>		<b>Color</b>	■ BLACK
<b>Type</b>	LEAFLET		
<b>Date</b>	20/09/2023		
<b>Artwork operator</b>	Nurit Assayag		
<b>Job no.</b>	SO23000513		

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## Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

### Aldara 5%, cream

#### Active ingredient:

Imiquimod 5%

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

#### 1. What is this medicine intended for?

Aldara cream is used in a different way for each of the three indications for which it is used. Your doctor may prescribe you Aldara to treat:

- warts on the genitals or around the anus (*condylomata acuminata*) in adults.
- actinic keratosis* in adults with a normal immune system.
- superficial basal cell carcinoma* in adults with a normal immune system, in cases where a surgical procedure is not recommended.

Aldara helps your body's immune system produce natural substances, which help your body fight cancer cells, actinic keratosis, or the virus that has caused your warts.

**Therapeutic group:** immunomodulatory medicines (modulators of the immune response).

#### 2. Before using this medicine

##### Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient Imiquimod or to any of the other ingredients in this medicine (listed in section 6, 'Additional information' of this leaflet).

##### Special warnings about using this medicine

- If you have previously used Aldara or other similar medicines, tell your doctor before starting treatment with Aldara.

- Tell your doctor if you suffer from autoimmune disorders.
- Tell your doctor if you know you have abnormal blood counts.

- If you have had an organ transplant.
- Do not use Aldara until the skin has healed after previous medicinal or surgical treatment.

- Avoid contact of the cream with the eyes, lips, and nostrils. In case of contact with these areas, rinse the area with water.
- This medicine is for external use only.

- Do not use the cream beyond the recommended time, quantity and frequency.

- Do not cover the treated area with bandages or other dressings after you have applied Aldara.

- If the treated area becomes too uncomfortable, wash the cream off with mild soap and water. As soon as the area is better you may restart your Aldara treatment.
- Because of the way Aldara works, there is a possibility that the cream may worsen existing inflammation in the treatment area.

- During your Aldara treatment and until completely healed, the treated area may appear very different from normal skin.

If you are being treated with Aldara for genital and anal warts, follow these additional precautions:

- Men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If this area is not washed daily, the foreskin may be more likely to show signs of tightness, swelling and peeling. This will cause difficulty in pulling it back. If these symptoms occur, stop the treatment immediately and call your doctor.

- Do not use on open sores. Wait until the sores have healed.

- If you have internal warts, do not use the cream on internal areas such as the opening of the urethra, the vagina, the cervix, or anus.

- Tell your doctor if you have problems with your immune system, either due to illness or because of the medicines you are already taking, because with these conditions Aldara should not be used for more than one course of treatment.

- If you are HIV positive, you should inform your doctor, as Aldara has not been shown to be as effective in these patients.

- If you decide to have sexual relations while you still have warts, apply Aldara after—not before—sexual relations.

- Aldara may weaken condoms and diaphragms, therefore wash the cream off the area before engaging in sexual relations.

- Remember, Aldara does not protect against giving HIV or other sexually transmitted diseases to someone else.

If you are being treated for actinic keratosis or basal cell carcinoma, follow these additional precautions:

- Do not use sunlamps or tanning beds and avoid exposure to sunlight as much as possible during treatment with Aldara cream. Use sunscreen lotion and wear protective clothing and wide brimmed hats when outdoors in the daytime.

#### Children and adolescents

Use of Aldara in children and adolescents is not recommended.

#### Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

There are no medicines known to be unsuitable for use during treatment with Aldara cream.

#### Pregnancy, breast-feeding, and fertility

You must consult your doctor if you are pregnant or are planning to have a baby. Your doctor will evaluate the risks and benefits of using Aldara during pregnancy. Studies in animals do not indicate direct or indirect harmful effects in pregnancy.

Do not breast-feed during treatment with Aldara, as it is not known whether the active ingredient *Imiquimod* is secreted in human milk.

#### Driving and using machines

Aldara has no or negligible influence on the ability to drive and use machines.

#### Important information about some of this medicine's ingredients

Aldara contains:

- Methyl hydroxybenzoate (E218)* and *propyl hydroxybenzoate (E216)*, which may cause allergic reactions (possibly delayed)
- Cetyl alcohol* and *stearyl alcohol*, which may cause local skin reactions (e.g. *contact dermatitis*)
- Benzyl alcohol*, which may cause allergic reactions and mild local irritation.

#### 3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

- Before going to bed, wash your hands and the treated area with mild soap and water. Dry the area.
- Open a new sachet and squeeze some Aldara cream onto your fingertip.
- Apply a thin layer of Aldara cream onto the clean and dry area to be treated, according to your doctor's directions. Rub gently into the skin until the cream vanishes.
- Each sachet is for a single use. After you have used it, throw away the opened sachet. Wash hands with soap and water.
- Leave Aldara cream on the treated area as long as advised by your doctor. Do not shower or bathe while the cream is on your skin.
- When your daily treatment is complete, wash Aldara cream off the treated area with mild soap and water.

#### Aldara Cream Application Instructions



Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

##### If you are being treated for genital and anal warts

- Before going to bed, apply the cream to the (clean and dry) warts and rub gently into the skin until the cream vanishes.
- Apply the cream once daily, 3 times per week (for example, Sunday, Tuesday, and Thursday). Treatment duration can be between 4–12 weeks.
- Leave Aldara cream on the warts for 6–10 hours; do not shower or bathe during this time.
- After 6–10 hours, wash the area where Aldara cream was applied with mild soap and water.
- One sachet contains enough cream to cover a wart area of 20 cm<sup>2</sup>.
- Continue to use Aldara as instructed by your doctor until your warts have completely gone (half the females who clear will do so in 8 weeks, half the males who clear will do so in 12 weeks, but in some patients the condition improves as early as 4 weeks).

- Do not use Aldara for more than 16 weeks for each episode of warts.

Men with warts under the foreskin should pull the foreskin back each day and wash underneath it (see section 2 'Special warnings about using this medicine').

##### If you are being treated for basal cell carcinoma

- Before going to bed, apply the cream to the (clean and dry) affected area and about 1 cm around it; rub gently into the skin until the cream vanishes.
- Apply the cream once daily, 5 times a week (for example Sunday, Monday, Tuesday, Wednesday, and Thursday) for 6 weeks.

- Leave Aldara cream on the skin for about 8 hours; do not shower or bathe during this time.

- After 8 hours, wash the area where Aldara cream was applied with mild soap and water.

##### If you are being treated for actinic keratosis

- Before going to bed, apply the cream to the (clean and dry) affected area once daily, 3 times a week (for example Sunday, Tuesday, and Thursday); rub gently into the skin until the cream vanishes.

- Leave Aldara cream on the skin for about 8 hours; do not shower or bathe during this time.

- After 8 hours, wash the area where Aldara cream was applied with mild soap and water.

- One sachet contains enough cream to cover an area of 25 cm<sup>2</sup>.

- Continue treatment for 4 weeks.

- Four weeks after finishing the first course of treatment, your doctor will assess the condition of your skin. If the lesions have not all disappeared, a further 4 weeks of treatment may be necessary.

##### If you accidentally apply a higher dosage

wash the area with mild soap and water. When the skin reaction has gone you may apply the cream again.

If you or a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to apply the medicine at the scheduled time, apply the next dose as soon as you remember. Do not apply the cream more than once per day.

Adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

If you have any further questions about using this medicine, consult your doctor or pharmacist.

#### 4. Side effects

Like with all medicines, using Aldara may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

- Skin colour in the treated area may change while you are taking this medicine. While these changes have tended to improve with time, in some patients they may be permanent.
- A lowering of blood counts, experienced by some patients, might make you more susceptible to infections, make you bruise more easily or cause fatigue. If you notice any of these symptoms, tell your doctor.

- If your skin reacts badly when using Aldara cream, stop applying the cream, wash the area with mild soap and water and contact your doctor or pharmacist.
- Serious skin reactions have been reported rarely. If you notice lesions or spots on your skin that start out as small red dots and then spread gradually, possibly with symptoms such as itching, fever, overall ill feeling, achy joints, vision problems, burning, painful or itchy eyes and mouth sores, stop using Aldara and contact your doctor immediately.

- Some patients who suffer from autoimmune disorders (a condition in which the immune system attacks an organ, substance, or system in your body) may experience worsening of their condition. If you notice any change in your condition during treatment with Aldara cream, tell your doctor.

- A small number of patients have experienced hair loss in the treated area or around it.

- Many side effects of Aldara are due to its local action on the affected area, and they are a sign that the medicine is working as intended.

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

#### 5. How to store the medicine?

• Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

• Do not use the medicine after the expiry date (exp. date) which is stated on the outer package. The expiry date refers to the last day of that month.

• Store below 25°C.

• Sachets should not be re-used once opened.

• Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### 6. Additional information

• The active ingredient in this medicine is *Imiquimod*. Each sachet contains 250 mg cream (100 mg cream contains 5 mg *Imiquimod*).

In addition to the active ingredient *Imiquimod*, this medicine also contains:

Purified water, Isostearic acid, Polysorbate 60, Stearyl alcohol, White soft paraffin, Cetyl alcohol, Benzyl alcohol, Glycerol, Sorbitan stearate, Xanthan gum, Methyl hydroxybenzoate, Propyl hydroxybenzoate.

• The tablet in the pack contains:

Each sachet contains 250 mg of a white to light yellow cream. Each box contains 12 single-use sachets.

#### Registration holder's name and address:

Megapharm Ltd., 15 HaTidhar St., Ra'anana, Israel.

#### Manufacturer's name and address:

Kindeva Ltd., Loughborough, England.

This leaflet was revised in May 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 114-44-29675.

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