

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

This medicine is dispensed with a doctor's prescription only

## **Aquimod cream 5%**

### **Active ingredient and its quantity:**

Each 0.25 gram sachet contains:

imiquimod 12.5 mg

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?**

Aquimod Cream 5% cream is used differently for each of the three indications for which the medicine is intended. Your doctor may prescribe you Aquimod Cream 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.

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

Imiquimod helps the immune system produce natural substances, which help your body fight cancer cells, actinic keratosis, or the virus that causes warts.

### **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 (see section 6).

### **Special warnings about using this medicine**

- If you have previously been treated with Aquimod Cream 5% or similar medicines, tell your doctor before starting treatment with Aquimod Cream 5%.
- Tell your doctor if you know of immune system problems.
- Tell your doctor if you know you have abnormal blood counts.
- Tell your doctor if you have had an organ transplant.
- Do not use Aquimod Cream 5% until the skin has healed after previous medicinal or surgical treatment.
- Avoid contact with the eyes, lips, and nostrils. If the cream comes into contact with these areas, rinse the area with water.
- 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 Aquimod Cream 5%.
- If the treated area becomes too uncomfortable, wash the area to which you applied Aquimod Cream 5% with mild soap and water. As soon as the area is better you may restart your Aquimod Cream 5% treatment.
- Because of the way Aquimod Cream 5% works, existing local inflammatory conditions in the treated area may worsen.
- During your treatment with Aquimod Cream 5% and until completely healed, the treated area may appear very different from normal skin.

If you are being treated with Aquimod Cream 5% for genital and anal warts, please note these additional precautions:

- Men treating warts under the foreskin should pull the foreskin back each day and wash area underneath it every single day. If this area is not washed daily, the foreskin may be tight, swollen and it may peel. As a

result, it will be difficult to pull the foreskin back. If these symptoms appear, stop the treatment and contact your doctor.

- Do not use on open sores. Wait until the sores have healed.
- In case of internal warts, do not use the cream on internal areas such as the opening of the urethra, vagina, cervix, or anus.
- Tell your doctor if you have problems with your immune system, due to illness or because of the medicines you are taking, because with these conditions Aquimod Cream 5% should not be used for more than one course of treatment.
- Tell your doctor if you are HIV positive, as Aquimod Cream 5% has not been shown to be effective in these patients.
- If you decide to have sexual relations while you still have warts, apply the cream after—not before—having intercourse.
- Aquimod Cream 5% may make condoms and diaphragms less effective, therefore wash the cream off the area before engaging in sexual relations.
- Remember, Aquimod Cream 5% does not protect against infecting other people with HIV or other sexually transmitted diseases.

If you are being treated with Aquimod Cream 5% for actinic keratosis or basal cell carcinoma, please note these additional precautions:

- Do not use sunlamps or tanning beds and avoid exposure to sunlight as much as possible during treatment with Aquimod Cream 5%. Use sunscreen and wear protective clothing and wide-brimmed hats when outdoors in the daytime.

### **Children and adolescents**

Treatment with Aquimod Cream 5% in children and adolescents is not recommended.

### **Drug interactions**

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

There are no known medicines whose use during treatment with Aquimod Cream 5% Cream is not recommended.

### **Pregnancy and breast-feeding**

Consult your doctor if you are pregnant or are planning to become pregnant. Your doctor will evaluate the risks and benefits of using Aquimod Cream 5% during pregnancy. Animal studies have not shown direct or indirect harmful effects during pregnancy.

Do not breast-feed during treatment with Aquimod Cream 5%, as it is not known whether the active ingredient imiquimod is secreted in breast milk or not.

### **Driving and using machines**

The medicine has no effect on the ability to drive and use machines.

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

The medicine contains:

- **Methyl paraben and propylparaben**, which may cause allergic reactions (possibly delayed reactions).
- **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. The medicine contains benzyl alcohol at a concentration of 2% w/w.

## **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. Only your doctor will determine your dose and how you should take this medicine.

General instructions:

1. Before going to bed, wash your hands and the treated area with mild soap and water. Dry the area.
2. Open a new sachet, squeeze it and place Aquimod Cream 5% on your fingertip.
3. Apply a thin layer of Aquimod Cream 5% onto the intended area when it is clean and dry, according to your doctor's instructions. Gently rub the cream into the skin until it vanishes.
4. Each sachet is for a single use. After use, throw away the opened sachet. Wash your hands with soap and water.

5. Leave Aquimod Cream 5% on the treated area according to your doctor's recommendation. Do not shower while the cream is on your skin.
6. When your daily treatment is complete, wash the area to which you applied Aquimod Cream 5% with mild soap and water.

Do not swallow. The medicine is intended for external use only.

The recommended dosage is usually:

For external local treatment of genital and anal warts

1. Before going to bed, apply the cream to the (clean and dry) warts and rub gently into the skin until the cream vanishes.
2. Apply the cream once daily, 3 times per week (for example, Sunday, Tuesday, and Thursday). Treatment duration can be 4–12 weeks.
3. Leave Aquimod Cream 5% on the warts for 6-10 hours; do not shower during this time.
4. After 6-10 hours, wash the area where Aquimod Cream 5% was applied with mild soap and water.
5. One sachet contains enough cream to cover a wart area of 20 cm<sup>2</sup>.
6. Continue to use Aquimod Cream 5% as instructed by your doctor until your warts are gone (half the women who recover from treatment with Aquimod Cream 5% will recover within 8 weeks, half the men who recover will recover within 12 weeks, but there are patients whose medical condition improves in just 4 weeks).
7. Do not use Aquimod Cream 5% for more than 16 weeks for each outbreak of warts.

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

For treatment of basal cell carcinoma

1. Before going to bed, apply the cream to the (clean and dry) area requiring treatment and about 1 cm around it; rub gently into the skin until the cream vanishes.
2. Apply the cream once daily, 5 times a week (for example Sunday, Monday, Tuesday, Wednesday, and Thursday) for 6 weeks.
3. Leave Aquimod Cream 5% on the skin for 8 hours; do not shower during this time.
4. After 8 hours, wash the area where Aquimod Cream 5% was applied with mild soap and water.

For treatment of actinic keratosis

1. Before going to bed, apply the cream to the (clean and dry) area requiring treatment once daily, 3 times a week (for example Sunday, Tuesday, and Thursday), and rub gently into the skin until the cream vanishes.
2. Leave Aquimod Cream 5% on the skin for 8 hours; do not shower during this time.
3. After 8 hours, wash the area where Aquimod Cream 5% was applied with mild soap and water.
4. One sachet contains enough cream to cover an area of 25 cm<sup>2</sup>.
5. Continue treatment for 4 weeks.
6. Four weeks after finishing the first course of treatment, your doctor will assess the condition of your skin. If the lesions have not disappeared, a further 4 weeks of treatment may be necessary.

**Do not exceed the recommended dose.**

**If you accidentally apply a higher dosage**, wash the area with mild soap and water. When your skin is no longer irritated, 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 a 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**

As with any medicine, using Aquimod Cream 5% may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

- 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 slowly, possibly with itching, fever, overall ill feeling, achy joints, vision problems, burning, painful or itchy eyes and mouth sores, **stop using Aquimod Cream 5% and contact your doctor immediately.**
- If you experience a bad skin reaction while using Aquimod Cream 5%, **stop applying the cream**, wash the area with mild soap and water, **and contact your doctor or pharmacist.**
- A lowering of blood counts experienced by some patients might cause increase in susceptibility to infections, tendency to bruises and fatigue. If you experience these symptoms, **contact your doctor.**
- **Tell your doctor or pharmacist right away** if you do not feel well during treatment with Aquimod Cream 5%.
- 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. **Tell your doctor** if you notice any change in your condition during treatment with Aquimod Cream 5%.
- A small number of patients have experienced hair loss in the treated area or around it.
- Many side effects of Aquimod Cream 5% are related to the local action of the medicine on the affected area and indicate that it is working as intended.
- When using the medicine, the skin colour in the treated area may change. While these changes tend to improve with time, in some patients they may be permanent.

**If you are being treated with Aquimod Cream 5% for genital or anal warts:**

Most of the side effects of Aquimod Cream 5% are due to its local action on your skin.

Very common side effects - affect more than one in ten users:

- redness, peeling skin, flaking skin, swelling, thickening of the skin, skin sores, scabbing and bubbles under the skin.
- itching, burning sensation, localized pain in areas where the cream was applied.

Most of these effects are not severe and will resolve within about two weeks after treatment is stopped.

Common side effects - affect 1–10 in 100 users:

- headaches.

Uncommon side effects - affect 1–10 in 1,000 users:

- fever, flu-like symptoms, muscle and joint pain.
- prolapse of the womb, pain during intercourse in women, erection difficulties in men.
- increased sweating, nausea and vomiting.
- digestive system symptoms.
- ringing in the ears.
- flushing, tiredness, dizziness, migraines, pins and needles, insomnia, depression, loss of appetite.
- swollen glands, bacterial, viral or fungal infections, vaginal infections, including thrush.
- cough and cold with sore throat.

Very rare side effects - affect less than one in 10,000 users:

- severe and painful skin reactions, particularly in cases of overdose.
- painful skin reactions at the opening of the vagina, severe enough to make it difficult to pass urine. If this occurs you should seek medical assistance immediately.

**If you are being treated with Aquimod Cream 5% for basal cell carcinoma:**

Most of the side effects of Aquimod Cream 5% are due to its local action on your skin. Local skin reactions can be a sign that the medicine is working as intended.

Very common side effects - affect more than one in ten users:

- itchiness in the treated area.

Common side effects - affect 1–10 in 100 users:

- pins and needles, small swollen areas in the skin, local pain, burning, irritation, bleeding, redness or rash.
- If pus or other signs of infection appear, contact your doctor.
- If your skin becomes too uncomfortable during treatment, consult your doctor. Your doctor may recommend that you stop using Aquimod Cream 5% for a few days (a short rest from treatment).
- swollen glands, back pain.

Uncommon side effects - affect 1–10 in 1,000 users:

- changes in the treated area, such as: skin peeling, inflammation, swelling, scabbing of the skin, cracks in the skin, blisters, inflammation of the skin (dermatitis).
- irritability, nausea and vomiting, dry mouth, flu-like symptoms, tiredness.

**If you are being treated with Aquimod Cream 5% for actinic keratosis:**

Most of the side effects of Aquimod Cream 5% are due to its local action on your skin. Local skin reactions can be a sign that the medicine is working as intended.

Very common side effects - affect more than one in ten users:

- itchiness in the treated area.

Common side effects - affect 1–10 in 100 users:

- local pain, burning, irritation, redness.
- If there is pus or other signs of infection, contact your doctor.
- If your skin becomes too uncomfortable during treatment, consult your doctor. Your doctor may recommend that you stop using Aquimod Cream 5% for a few days (to have a short rest from treatment).
- headaches.
- Loss of appetite (anorexia), nausea.
- muscle pain, joint pain, and tiredness.

Uncommon side effects - affect 1–10 in 1,000 users:

- changes in the treated area, such as bleeding, inflammation, skin peeling, skin sensitivity, swelling, small swollen areas in the skin, pins and needles, scabbing of the skin, scarring, ulceration, a feeling of warmth or discomfort in the area.
- inflammation of the inner part of the nose, congested nose, flu or flu-like symptoms, sore throat, pain in extremities, fever, weakness or shivering.
- depression.
- eye irritation, swollen eyelids.
- diarrhoea.
- redness.
- swelling of the face, ulcers.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

**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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C. Protect against freezing.
- Use the sachet immediately after opening it. Dispose of the sachet with the remaining cream inside after use. Do not keep an open sachet for later use.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

**6. Additional information**

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

isostearic acid, polysorbate 60 (Tween 60), stearyl alcohol, white petrolatum, cetyl alcohol, benzyl alcohol, glycerin, xanthan gum (Xantural 75), sorbitan monostearate, methylparaben (methyl parahydroxybenzoate), propylparaben (propyl parahydroxybenzoate) and purified water.

**What the medicine looks like and contents of the pack:**

A smooth white-yellowish cream. The cream is packaged in a pack that contains 12 or 24 sachets of 0.25 grams, or in a tube containing 3 grams.

Not all pack sizes and types may be marketed.

**Manufacturer and registration holder:** Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

**Registration number of the medicine in the Ministry of Health's National Drug Registry:** 144.90.33114.00.

Revised in June 2024.

**For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:**



<https://israeldrugs.health.gov.il/#!/medDetails/144%2090%2033114%2000>

For a printed copy of the patient information leaflet in English, please contact the registration holder by email [Info@taro.com](mailto:Info@taro.com) or by phone 1-800-464-664.