

AQUIMOD 5%, CREAM

The active ingredient and its quantity:
Each 0.25 gram sachet contains:

Imiquimod 12.5 mg

For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

- For the wart indication, the medicine is not intended for patients under the age of 12 years.
- For the solar keratosis and superficial basal cell carcinoma indication, the medicine is not intended for patients under the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For local external treatment of warts (condylomata acuminata) in the area of the genitals and anal area in adults.
- Solar keratosis in adults with a healthy immune system.
- Superficial basal cell carcinoma in adults with a healthy immune system in cases where surgical procedures are less appropriate.

Imiquimod aids the immune system to produce natural substances that help the body fight causes of skin lesions.

Note: The method of treatment with Aquimod 5% is different for each of the three indications. It is very important to follow the doctor's instructions according to the purpose for which the cream is intended.

Therapeutic group: antiviral, anticancer.

2. BEFORE USING THE MEDICINE

<div><input checked="" type="checkbox"/> Do not use the medicine if:<ul style="list-style-type: none">• you are sensitive (allergic) to the active ingredient (imiquimod) or to any of the other ingredients in the medicine (please see section 6).</div>

Special warnings regarding use of this medicine:

- **Before treatment with Aquimod 5%, tell the doctor if:**
 - you used Aquimod 5% or similar preparations in the past.
 - you have known impaired function of your immune system.
 - you have an abnormal blood count.
- Do not use the cream before the skin has healed from previous medicinal treatment or surgical treatment.
- Avoid contact with the eyes, lips or nostrils. In case of contact between the medicine and the eyes, lips or nostrils – wash these areas thoroughly with water.
- The medicine is only intended for use on the skin and is not intended for internal use.
- Do not use more cream, for longer and more frequently than recommended.
- Do not dress or block the treated area with a bandage or other dressings.
- If there is too much discomfort in the treated area, wash off the cream with mild soap and water. Immediately after the problem is resolved, you can resume using the cream.
- **When using Aquimod 5% to treat solar keratosis or superficial basal cell carcinoma, take heed of the following additional warnings:**
 - Avoid using sunlamps or tanning beds and avoid, as much as possible, exposure to the sun, throughout the course of treatment with Aquimod 5%. Use sunscreen and wear protective clothing and wide-brimmed hats when going outside during the day.
- **When treatment is intended for genital warts, take heed of the following additional warnings:**
 - Uncircumcised men treating warts under the foreskin should expose the glans penis (the tip of the penis) and wash the area each day. If the area is not washed well daily, the foreskin may tighten around the glans penis, swell and become damaged, making it difficult to pull it back. If you notice these signs – stop treatment immediately and refer to the doctor.
 - Genital warts are contagious; therefore, make sure that your partner is checked by a doctor.
 - If you have open sores – do not use Aquimod 5% until the sores have healed.
 - If you have internal warts – do not use Aquimod 5% in the urethra (the opening through which the urine passes), the vagina (birth canal), cervix (internal female organ) or anywhere within the anus (rectum).
 - Do not use this medicine for more than one treatment cycle if you have immune system problems due to an ailment or the medicines you are taking. If you think this applies to you, refer to the doctor.
 - If your HIV test was positive, you must inform the doctor, since Aquimod 5% is not as effective in HIV-positive patients.
 - If you decide to have intercourse while you still have warts, apply Aquimod 5% after and not before intercourse. Aquimod 5% may weaken condoms and diaphragms; therefore, do not leave the cream on during intercourse. Remember, use of Aquimod 5% does not protect against transmission of HIV virus or other sexually transmitted diseases to another person.
- Patients must know that due to the mode of action of Aquimod 5%, preexisting inflammations in the affected areas may become aggravated during the course of treatment.
- When using Aquimod 5% and until healing, the treated area may look significantly different than usual.

⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

There are no medicines known to be incompatible for use with Aquimod 5%.

⚠ Pregnancy and breastfeeding:

Do not use this medicine without consulting a doctor before starting treatment if you are pregnant or breastfeeding.

Tell the doctor if you are pregnant or are planning to become pregnant. The doctor will discuss with you the benefits and risks of using Aquimod 5% during pregnancy. Animal studies have not shown any direct or indirect harmful effect during pregnancy.

Do not breastfeed during the course of treatment with Aquimod 5%, since it is unknown whether the medicine is secreted into the breast milk.

⚠ Driving and operating machinery:

The medicine does not affect the ability to drive or to operate machinery.

⚠ Important information about some of the ingredients of the medicine:

Methylparaben and propylparaben may cause allergic reactions (delayed reactions may occur). Cetyl and stearyl alcohol may cause local skin reactions (e.g., contact dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
- Wash your hands thoroughly before and after using the cream. Do not cover the treated area with a bandage or other dressings after applying Aquimod 5%.
- Open a new sachet each time you use the cream. Throw out any remnants of the cream that remain in the sachet after use. Do not save an open sachet for later use.

The dosage and treatment regimen will be determined by the doctor only.

The duration and frequency of treatment differ for treatment of genital warts, solar keratosis or superficial basal cell carcinoma. See the specific instructions for each indication.

Do not exceed the recommended dose.

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

Instructions for use - General instructions:

For treatment of genital warts (Monday, Wednesday and Friday):

1. Before going to bed, wash your hands and the treatment area with mild soap and water and dry thoroughly.
2. Open a new sachet, squeeze on the sachet and place Aquimod 5% on the fingertip.
3. Apply a thin layer of Aquimod 5% onto the intended area which is clean and dry. Rub gently into the skin until the cream vanishes.
4. After use, throw away the open sachet and wash your hands with soap and water.
5. Leave Aquimod 5% on the treated area for 6-10 hours. Do not shower while the cream is on your skin.
6. After 6-10 hours, wash the area where Aquimod 5% was applied with mild soap and water.

Use Aquimod 5% three times a week. For example: use the cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover a wart area of 20 cm².

If there are warts under the foreskin, pull the foreskin back and wash the area underneath every day (see "Special warnings regarding use of this medicine" section).

Continue using Aquimod 5% according to the instructions until the warts have completely disappeared (in half the women, the warts will disappear within 8 weeks, in half the men, the warts will disappear within 12 weeks, but in some patients, warts can disappear within 4 weeks only).

Do not use Aquimod 5% for more than 16 weeks for each cycle of wart treatment.

If you feel the effect of the medicine is too strong or too weak, refer to a doctor or pharmacist.

For treatment of superficial basal cell carcinoma (Monday, Tuesday, Wednesday, Thursday and Friday):

1. Before going to bed, wash your hands and the treatment area with mild soap and water and dry thoroughly.
2. Open a new sachet, squeeze on the sachet and place Aquimod 5% on the fingertip.
3. Apply Aquimod 5% to the intended area and about 1 cm around it. Rub gently into the skin until the cream vanishes.
4. After use, throw away the open sachet and wash your hands with soap and water.
5. Leave Aquimod 5% on the treated area for about 8 hours. Do not shower while the cream is on the skin.

6. After about 8 hours, wash the area where Aquimod 5% was applied with mild soap and water. Apply sufficient Aquimod 5% to cover the intended area and about 1 cm around it, for 5 consecutive days each week for 6 weeks. For example: apply the cream from Monday to Friday. Do not apply the cream on Saturday and Sunday.

For treatment of solar keratosis (Monday, Wednesday and Friday):

1. Before going to bed, wash your hands and the treatment area with mild soap and water and dry thoroughly.
2. Open a new sachet, squeeze on the sachet and place Aquimod 5% on the fingertip.
3. Apply Aquimod 5% to the intended area. Rub gently into the skin until the cream vanishes.
4. After use, throw away the open sachet and wash your hands with soap and water.
5. Leave Aquimod 5% on the treated area for about 8 hours. Do not shower while the cream is on the skin.
6. After about 8 hours, wash the area where Aquimod 5% was applied with mild soap and water.

Apply Aquimod 5% three times per week. For example: apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover an area of 25 cm². Continue treatment for 4 weeks. After 4 weeks, the doctor will check the condition of your skin. If not all the lesions have disappeared, there may be need for an additional 4-week treatment cycle.

If you accidentally used more than necessary, wash the excess amount with mild soap and water. After the skin reaction vanishes, you can continue treatment. If you or your child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the required time, apply when you remember and continue according to the regular schedule. Do not apply more than once a day.

Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

The frequency of side effects is classified as follows:

Very common side effects (may occur in more than 1 in 10 patients)

Common side effects (may occur in fewer than 1 in 10 patients)

Uncommon side effects (may occur in fewer than 1 in 100 patients)

Rare side effects (may occur in fewer than 1 in 1,000 patients)

Very rare side effects (may occur in fewer than 1 in 10,000 patients).

As with any medicine, use of Aquimod 5% may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Discontinue use of the medicine and refer to a doctor immediately:

- If you suffer from severe skin reactions (rare): appearance of bruises or spots on the skin that begin as red areas that develop to what look like "target" signs and may be accompanied by itching, fever, overall ill feeling, joint pains, vision disturbances, burning, pain or itching in the eyes and oral ulcers.
 - When Aquimod 5% is used for the treatment of genital warts: in uncircumcised men – if you notice tightening of the foreskin toward the glans penis, and its swelling.
- Refer to a doctor as soon as possible:**
- If you do not feel well during the course of treatment with Aquimod 5%.
 - In women treated for genital warts – if you are suffering from a severe and painful skin reaction at the opening of the vagina that makes it difficult to pass urine (very rare).
 - If you notice a tendency to develop infections, appearance of skin bruises and tiredness. This can indicate reduced blood count.
 - In case of irritation or severe reaction, wash thoroughly with water and soap and refer to a doctor. If the skin reaction causes too much discomfort during the course of treatment, the doctor may recommend that the treatment be discontinued for a few days.
 - If there is pus or other signs of infection.

Additional side effects:

- Changes in skin color in the treated area. These changes usually improve with time, but may be permanent in some patients.
- There may be hair loss in or around the treated area.

If you are using the medicine to treat genital warts:

Many side effects of Aquimod 5% are due to local skin reactions.

Very common side effects: redness, wearing away of the skin, flakiness of the skin and swelling. Hardening under the skin, small open sores, a crust that forms during healing and small bubbles under the skin may also occur. You might also feel itching, burning or pain in the area where you have applied the cream. Most of these effects are mild and the skin returns to normal about two weeks after stopping treatment.

Common side effects: headache.

Uncommon side effects: fever and flu-like symptoms, joint and muscle pains, prolapse of the womb, pain on intercourse in women, erection difficulties, increased sweating, feeling sick, stomach and bowel symptoms, ringing in the ears, flushing, tiredness, dizziness, migraine, pins and needles, insomnia, depression, loss of appetite, swollen glands, bacterial, viral or fungal infections (e.g., cold sores), vaginal infection including thrush, cough and cold with sore throat.

Very rare side effects: severe and painful reactions have occurred, particularly when using more cream than recommended.

If you are using the medicine to treat superficial basal cell carcinoma:

Many side effects of Aquimod 5% are due to local skin reactions. Local skin reactions can be a sign that the medicine is working as intended.

Very common side effects: slight itching of the treated area.

Common side effects: pins and needles, small swollen areas in the skin, pain, burning, irritation, bleeding, redness or rash. Swollen glands or black pain.

Uncommon side effects: changes in the treated area (discharge, inflammation, swelling, scabbing, skin breakdown, blisters, dermatitis) or irritability, feeling sick, dry mouth, flu-like symptoms and tiredness.

If you are using the medicine to treat actinic keratosis:

Many side effects of Aquimod 5% are due to local skin reactions. Local skin reactions can be a sign that the medicine is working as intended.

Very common side effects: slight itching of the treated area.

Common side effects: pain, burning, irritation or redness, headache, loss of appetite, nausea, muscle pain, joints pain and tiredness.

Uncommon side effects: changes at the application site (bleeding, inflammation, discharge, sensitivity, swelling, small swollen areas on the skin, pins and needles, scabbing, scarring, ulceration, a feeling of warmth or discomfort) or inflammation of the lining of the nose, stuffy nose, flu or flu-like symptoms, depression, eye irritation, swelling of the eyelids, throat pain, diarrhea, actinic keratosis, redness, swelling of the face, ulcers, pain in extremity, fever, weakness or shivering.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Protect from freezing.
- Discard the remnants of the cream that remain in the sachet after use. Do not keep an open sachet for later use.
- Do not discard medicines in the waste bin or waste water. Ask the pharmacist how to discard of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Isostearic Acid, Benzyl Alcohol, Methylparaben (Methyl Parahydroxybenzoate), Propylparaben (Propyl Parahydroxybenzoate), Cetyl Alcohol, Stearyl Alcohol, White Petrolatum, Sorbitan Monostearate, Polysorbate 60 (Tween 60), Glycerin, Xanthan Gum (Xantural 75) and Purified Water.

What the medicine looks like and the contents of the package:

The cream is white-yellowish. The cream is packaged in 0.25 gram sachets.

Manufacturer and License holder: Taro Pharmaceutical Industries Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 144.90.33114

This leaflet was checked and approved by the Ministry of Health in May 2015.



AQUIMOD
Cream