PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Perrimod Cream 5%

The cream contains a 5% concentration of Imiquimod.
Inactive ingredients: See section 6 in the leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. Keep this leaflet since you may want to read it again. 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 medical condition is similar. If one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

The manner of treatment with Perrimod cream is different for each of its three indications. The doctor may prescribe Perrimod cream for the treatment of:

- Warts (condyloma acuminata) on the genitals and around the anus in adults.
- Actinic keratosis in adults with a healthy immune system.
- Superficial basal cell carcinoma in adults with a healthy immune system, in cases in which a surgical procedure is not recommended.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- You are **sensitive** (allergic) to the active ingredient imiquimod or to any of the additional ingredients found in the medicine (see section 6: Further Information, in the leaflet).

Use in children and adolescents:
This medicine is not recommended for children and adolescents.

Special warnings regarding use of this medicine:
Take special care:

- If you have previously been treated with Perrimod cream or other similar preparations inform your doctor before starting this treatment.
- If you suffer from problems with your immune system, inform the doctor.
- Do not use Perrimod cream until the area to be treated has healed after surgical or previous drug treatment.
- Avoid contact with the eyes, lips and nostrils. In the event of accidental contact, remove the cream by rinsing with water.
- Do not use more cream than the doctor has advised.
- Do not bandage the treated area after you have applied Perrimod cream.
- If you experience significant discomfort in the treated site, wash the cream off with mild soap and water. As soon as you begin to feel an improvement, you may begin to reapply Perrimod cream.
- Tell the doctor if you have an abnormal blood count.

Because of the way Perrimod cream works, there is a possibility that the cream may worsen existing inflammation in the treated area.

If you are being treated with Perrimod cream for genital warts follow these additional precautions:

- Men being treated for warts under the foreskin – the foreskin should be pulled back to expose the crown and clean the area daily. If not washed daily the foreskin may be more likely to show signs of tightness, swelling and wearing away of the skin and result in difficulty in exposing the crown. If these symptoms occur, stop the treatment immediately and refer to the doctor.
- Do not use on open sores. Wait until after the sores have healed before beginning treatment with Perrimod cream.
- Do not use Perrimod cream for treating internal warts in the urethra, the vagina (birth canal), the cervix (internal female organ), or anywhere inside your anus (rectum).
- Do not use this medicine for more than one course of treatment if you suffer from a problem with your immune system, either due to an illness or to medicines you are taking. If you think this section applies to you, please contact the doctor.
- You must inform the doctor if you are an HIV carrier. Perrimod cream has not been shown to be effective in this group of patients.
- If you decide to have sexual relations, despite the warts, apply Perrimod cream after - not before - sexual activity. Perrimod cream may harm the effectiveness of condoms and vaginal diaphragms, therefore the cream should be carefully washed off the skin beforehand.
- Remember, Perrimod cream does not protect against infecting others with AIDS or other sexually transmitted diseases.

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

- During treatment with Perrimod cream, avoid using sunlamps or tanning beds, and avoid exposure to sunlight as much as possible. Apply protective sunscreen and wear protective clothing and a wide brimmed hat when outdoors during daylight hours.

During use with Perrimod cream and until the sores are healed, the treatment area is likely to appear different than healthy skin.

If you are taking, or have recently taken, other medicines including non-prescription medicines and food supplements, tell the doctor or pharmacist.
There are no medicines known to be incompatible during treatment with Perrimod cream.

Pregnancy and breastfeeding:

- Consult with a doctor before using any medicine.
- Consult with the doctor if you are pregnant or planning to become pregnant. The doctor will discuss the risks and benefits of using Perrimod cream during pregnancy. Studies in animals did not indicate direct or indirect harmful effects during use of Perrimod cream in pregnancy.
- Do not use Perrimod cream if you are breastfeeding. It is not known whether the active ingredient imiquimod is secreted in breast milk.

Important information about the following inactive ingredients in Perrimod cream:

- Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE THE MEDICINE?

Children and adolescents:

- Perrimod cream is not recommended for use in children and adolescents.

Adults:

- Always use according to doctor's instructions. Do not exceed the dosage prescribed for you by the doctor. Check with the doctor or pharmacist if you are not sure. Do not swallow. For external use only.
- Wash hands carefully before and after applying Perrimod cream.
- Do not cover the treated area with bandages or any other dressings after you have applied Perrimod cream.
- Open a new sachet of Perrimod cream for every use. Dispose of the sachet after use. Do not save the sachet for use at a later date.

The duration and frequency of treatment differ for genital warts, basal cell carcinoma and actinic keratosis (see specific instructions for each indication).

If you are being treated with Perrimod cream for genital warts:
Instructions for Use -

1. Apply the cream before going to bed. Wash your hands and the treated area with mild soap and water. Dry thoroughly.
2. Open a new sachet and place some cream onto your fingertip.
3. Apply a thin layer of cream onto the wart area when it is clean and dry. Rub gently into the skin until the cream vanishes.
4. After applying the cream, throw away the opened sachet and wash hands with soap and water.
5. Leave the cream on the warts for 6 to 10 hours. Do not shower during the time that the cream is on the skin.
6. After 6 to 10 hours wash the area where Perrimod cream was applied with mild soap and water.

Apply Perrimod cream 3 times per week. For example, apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to sufficiently cover a wart area of 20 cm^2.
Male treating warts under the foreskin should pull the foreskin back each day and wash underneath it (see section 2 "Take special care").
Continue to use Perrimod cream, according to doctor's instructions, until the warts have completely disappeared (half of the females being treated with Perrimod cream will heal within 8 weeks, half of the males will heal within 12 weeks, but in some patients the medical condition may improve as early as 4 weeks only).
Do not use Perrimod cream for more than 16 weeks per treatment period.
If you feel that the effect of Perrimod cream is too strong or too weak, consult with the doctor or pharmacist.

If you are being treated for actinic keratosis:

1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and place some cream onto your fingertip.
3. Apply Perrimod cream to the affected area. Rub gently into the skin until the cream vanishes.
4. After application of the cream, throw away the opened sachet. Wash hands with soap and water.
5. Leave Perrimod cream on the skin for about 8 hours. Do not shower during this time.
6. After 8 hours, wash the area where Perrimod cream was applied with mild soap and water.

Apply Perrimod cream 3 times per week. For example: apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to sufficiently cover a wart area of 25 cm^2.
Continue treatment for four weeks. Four weeks after finishing this first treatment, the doctor will assess your skin condition. If the skin lesions have not disappeared, a further four-weeks treatment session may be necessary.

If you are being treated with Perrimod cream for superficial basal cell carcinoma:

1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and place some cream onto your fingertip.
3. Apply a layer of cream to cover the affected area and about 1 cm around the affected area.
4. Rub gently into the skin until the cream vanishes.
5. After application, throw away the opened sachet. Wash hands with soap and water.
6. Leave the cream on the treated area for about 8 hours. Do not shower during this time.
7. After 8 hours, wash the area where Perrimod cream was applied with mild soap and water.

Treatment will be given for 5 consecutive days each week for a total of 6 weeks. For example, apply the cream from Monday to Friday. Do not apply the cream on Saturday and Sunday.

If you use more Perrimod cream than you should:
Wash well with mild soap and water. When any skin reaction has dissipated, you may continue with treatment.
If you accidentally swallowed or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to apply Perrimod cream:
If you forget to apply the cream at the regular time, apply the cream as soon as you remember and then continue your regular treatment. Do not take a double dose. Do not apply the cream more than once per day.
Be sure to adhere to the treatment regimen as recommended by the doctor.
If you have any further questions regarding the use of Perrimod cream, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Perrimod cream 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.
Tell the doctor or pharmacist as soon as possible if you do not feel well while you are using Perrimod cream.
Some patients have experienced changes in skin color in the treated area. While these changes are usually transient and improve with time, in some patients they may be permanent.
If your skin reacts badly to use of Perrimod cream, stop treatment, wash the area with mild soap and water and contact the doctor or pharmacist.
In some patients the use of Perrimod cream causes a decrease in the blood count. A decrease in the blood count might make you more susceptible to infections, cause fatigue more than usual or make you bruise more easily. If you notice any of these symptoms, contact your doctor.
Serious skin reactions have only been reported rarely. If you experience skin lesions or spots on your skin that start out as small red areas and progress with time to look like mini targets, possibly with symptoms such as itching, fever, burning, overall ill feeling, achy joints, vision problems, painful or itchy eyes and mouth sores, stop using Perrimod cream and refer to the doctor immediately.
A small number of patients have experienced hair loss at the treatment site or surrounding area.
If any of the side effects gets serious, or if you suffer from any side effects not mentioned in this leaflet, consult with the doctor or pharmacist.

If you are being treated with Perrimod cream for genital warts:
Most of the side effects of Perrimod cream are due to its local action on the skin.

Appearing very frequently:
Very common effects include redness, wearing away of the skin, flakiness and swelling.
There also may appear hardening under the skin, small open sores, a crust that forms in the treated area during healing, and small bubbles under the skin.
Itching, burning or pain may appear during treatment with Perrimod cream.
Most of these skin reactions are mild and the skin will return to normal within about 2 weeks after stopping treatment.

Appearing frequently:
Some patients have experienced headache, irregular fever and flu-like symptoms such as joint and muscle pain, prolapse of the womb, pain on intercourse in females, erection difficulties, increase in sweating, nausea, gastrointestinal symptoms, ringing in the ears, flushing, tiredness, dizziness, migraine, tingling sensation, insomnia, depression, loss of appetite, swollen lymph nodes, bacterial, viral and fungal infections (e.g. cold sores), vaginal infection including thrush, cough and colds with sore throat.

Appearing very rarely:
Severe and acute reactions have occurred, when more Perrimod cream than recommended was used.
If you experience a severe skin reaction at the opening of the vagina with pain or difficulty passing urine or inability to pass urine, contact the doctor immediately.

If you are being treated with Perrimod cream for actinic keratosis:

Appearing very frequently:
The treated area may be slightly itchy.

Appearing frequently:
These effects include: pain, burning, irritation and redness.
If you experience too much discomport in the skin during the course of treatment, consult with the doctor. The doctor may advise you to stop applying Perrimod cream for a few days (i.e. to have a short rest from treatment).
If there is pus or any other symptom of infection, consult with the doctor. Apart from reactions in the skin, other effects may occur: headache, anorexia (loss of appetite), nausea, muscle pain, joint pain and fatigue.

Appearing infrequently:
Some patients experienced changes at the application site (bleeding, inflammation, discharge, sensitivity, swelling, small swollen areas in the skin, tingling sensation, scarring, scabbing, ulceration or 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 eyelid, throat pain, diarrhea, actinic keratosis, redness, swelling of the face, ulcers, pain in extremities, fever, weakness or shivering.

If you are being treated with Perrimod cream for superficial basal cell carcinoma:
Most of the side effects of Perrimod cream are due to its local action on the skin. Local skin reactions can be a sign that the drug is working as intended.

Appearing very frequently:
Slight itch.

Appearing frequently:
These effects include: tingling sensation, small swollen areas in the skin, pain, burning, irritation or redness or rash.
If you experience too much discomport in the skin during the course of treatment, consult with the doctor. The doctor may advise you to stop applying Perrimod cream for a few days (i.e. to have a short rest from treatment).
If there is pus or any other symptom of infection, consult with the doctor. Apart from reactions in the skin, other effects including swollen lymph nodes and back pain may occur.

Appearing infrequently:
Some patients experienced changes at the application site (discharge, inflammation, sensitivity, swelling, scabbing, scarring, peeling skin, blisters, dermatitis) or irritability, feeling sick, dry mouth, flu or flu-like symptoms.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This preparation, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Each sachet is for a single use. Do not reuse an open sachet.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C.
Sachets should not be re-used once opened.
Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, Perrimod cream also contains the following inactive ingredients:
  Oleic Acid NF, Methylparaben NF, Propylparaben NF, Oleyl Alcohol NF, Polysorbate 60 NF, White Petrolatum USP, Cetyl alcohol NF, Stearyl alcohol NF, Sorbitan Monostearate NF, Glycerin USP, Benzyl alcohol NF, Xanthan gum NF, Purified water USP, EP.
- What does the medicine look like and what are the contents of the package:
  Perrimod 5% cream: Each sachet contains 0.25 g of cream. A box of Perrimod cream contains 12 or 24 single-use sachets.
- Registration holder and address: Perrigo Israel Pharmaceuticals Ltd, P.O.B. 16, Yeruham.
- Name and address of manufacturer: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- This leaflet was checked and approved by the Ministry of Health in: April 2013.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14972.33636