

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

This medicine is dispensed with a doctor's prescription only

Condylox[®]

0.5% solution

Composition:

Active ingredient:
podophyllotoxin 0.5%

Inactive ingredients and allergens—see section 6 'Additional information' in this leaflet.

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?

For treatment of external genital warts (condyloma acuminatum).

Therapeutic group: anti-viral.

The active ingredient podophyllotoxin is the therapeutically active component of podophyllin, a resin derived from the rootstock of the podophyllum species (Berberidaceae).

Podophyllotoxin inhibits cell division and has an anti-inflammatory effect.

2. Before using this medicine

Do not use this medicine:

- if you are hypersensitive (allergic) to podophyllotoxin or any of the other ingredients in this medicine listed in section 6
- in the case of inflamed or bleeding genital warts
- with concomitant use of other compounds containing podophyllotoxin
- during pregnancy and breast-feeding
- in children under 12 years of age

Special warnings about using this medicine:

Talk to your doctor or pharmacist before taking Condylox 0.5% solution.

- Condylox 0.5% solution is used exclusively for the treatment of genital warts. Condylox 0.5% solution must not be applied to other warts or moles. Contact with healthy skin should be avoided.

- Contact of this medicine with the eyes should be avoided. In case of contact with the eyes, you must immediately rinse with a lot of water and consult the doctor.
- Men: should use condoms until complete healing. The sexual partner should also be examined by a doctor.
- At the first signs of side effects and at the onset of pregnancy, report this to your doctor immediately.
- Women: should use this medicine with close medical supervision.
- Men: If you have many warts that cover an area that is larger than 4cm² (the size of a postage stamp), use this medicine with close medical supervision.

Children and adolescents:

This medicine should not be used in children under 12 years of age.

There is no experience using Condyllox 0.5% solution in adolescents aged 12-18 years.

Other medicines and Condyllox:

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

Concomitant treatment with other podophyllin-containing medicinal products should be avoided, as these also contain podophyllotoxin.

Using this medicine and alcohol consumption:

Avoid alcohol consumption during treatment. Consuming alcohol during therapy can lead to a great increase in adverse effects.

Pregnancy and breast-feeding:

Please report the occurrence of a pregnancy to your doctor immediately.

Condyllox 0.5% solution causes serious harm to an unborn child when used during pregnancy.

Condyllox 0.5% solution must not be used during pregnancy and breast-feeding.

Driving and using machines:

Condyllox 0.5% solution has no or negligible effect on the ability to drive and use machines.

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.

The recommended dosage is usually:

Treatment is administered twice daily (at intervals of 12 hours) on 3 consecutive days. Thereafter, a treatment-free period of 4 days should be observed.

Repeat the treatment until the genital warts disappear, for a maximum duration of 4 weeks.

If your treatment does not succeed after four cycles of treatment, please consult your doctor who will consider an alternative.

Do not exceed the recommended dose.

Method of administration

Application to skin

Before applying the solution, wash the areas of the body to be treated thoroughly with soap and water and dry gently. Apply the solution to the genital warts with a cotton swab. The cotton swab must only be used once!

Do not allow the solution to touch healthy surrounding skin or mucous membranes. Condyllox 0.5% solution must not be applied to warts that are not on the genitals.

Allow the solution to dry for a few minutes after application.

Do not wash the Condyllox 0.5% solution off the treated area. Allow the treated areas to dry before they come in contact with clothing.

Clean hands thoroughly after each treatment.

The treatment with Condyllox 0.5% solution can be carried out by you at home.

But, warts that cover an area larger than 4 cm² in men and warts in women must be treated under close medical supervision.

Note: Do not swallow! This medicine is for external use only.

The risk of developing adverse effects is increased in case of extensive treatment using excessive amounts over a prolonged period of time, or with treatment of bleeding or recently removed genital warts, or accidental application to intact skin or mucous membranes.

If you have accidentally applied a higher dose, clean the skin thoroughly with soap and water. In case of contact with the eyes, thoroughly rinse eyes with water.

If you have applied an overdose, or if 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 Condyllox at the scheduled time, do not apply a double dose. Apply the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting 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 Condyllox may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects (affect more than 1 in 10 users): local irritation of the treated mucosa such as itching, burning, pain, redness, ulceration, loss of the outer mucosal layer.

Rare side effects, the frequency of which is not known: adhesions and inflammation of the glans penis and foreskin.

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.

Reporting of side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the carton and bottle label. The expiry date refers to the last day of that month.
- Close tightly and prevent entry of air and moisture.
- Do not store above 25°C. Protect from light.
- Store in the original package.
- Use within 6 weeks of first opening but not longer than the product's expiry date.
- Caution! Flammable substance, keep away from fire!
- Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to throw away 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:
ethanol 96%, (S)-lactic acid, sodium (S)-lactate solution 60%.
- What the medicine looks like and contents of the pack:
Each Condyllox pack contains 3.5 ml clear, colourless solution in a glass vial, and cotton swabs for application.

Registration holder: Takeda Israel Ltd., 25 Eyal St., POB 4140, Petach-Tikva 4951125.

Manufacturer: Takeda Austria GmbH, St. Peter-Strasse 25, 4020 Linz, Austria.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 050-14-26541-00

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