

Condylox 0.5% solution for external use GI
PACKAGE LEAFLET: INFORMATION FOR THE USER
Condylox 0.5% solution for external use
Active ingredient: Podophyllotoxin

Read the entire package leaflet carefully before you start using this

medicine.

- Keep the package leaflet. You may want to read it again later.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects affect you significantly or if you notice side effects not listed in this package leaflet, please inform your doctor or pharmacist.

This package leaflet includes:

1. What is Condylox 0.5% solution and what is it used for?
2. What do you need to know before using Condylox 0.5% solution?
3. How to use Condylox 0.5% solution?
4. What side effects are possible?
5. How to store Condylox 0.5% solution?
6. Further information

1. WHAT IS CONDYLOX 0.5% SOLUTION AND WHAT IS IT USED FOR?

The active ingredient podophyllotoxin is the therapeutically active component of podophyllin, the resin from the rhizome of Podophyllum species (Berberidaceae).

Podophyllotoxin inhibits cell division and has anti-inflammatory effects. Condylox 0.5% solution is used for non-inflamed, non-bleeding genital warts (pointed condylomas) on the external genital area in women and men.

2. WHAT SHOULD YOU CONSIDER BEFORE USING CONDYLOX 0.5% SOLUTION? NOTE?

if you are hypersensitive (allergic) to podophyllotoxin or any of the other

- ingredients of Condylox 0.5% solution. on inflamed or bleeding genital warts
- with simultaneous use of other podophyllotoxin-containing
- preparations during pregnancy and breastfeeding
- in children under 12 years
- Special caution is required when using Condylox 0.5% solution,

as Condylox 0.5% solution is exclusively for the treatment of genital warts.

- since 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.
- as Condylox 0.5% solution must not come into contact with the eyes. If Condylox 0.5% solution does get into the eye, immediate rinsing with water should be performed and a doctor should be contacted.

- in male patients. They should use condoms until complete healing. The sexual partner should also be examined by a doctor.

KLGU 24.02.2014 Page 1 of 4 Takeda Austria

Condylox 0.5% solution for external use GI

- at the first signs of side effects and upon the onset of pregnancy. Please report this to your doctor immediately.
- There is no experience with the use of Condylox 0.5% solution in adolescents between 12 and 18 years. When using Condylox 0.5% solution with other medications

Simultaneous treatment with other podophyllin-containing preparations should be avoided, as these

also contain podophyllotoxin. Please inform your doctor or pharmacist if you are taking or have recently taken or used other medications, even if they are non-prescription.

When using Condylox 0.5% solution together with food and drinks prescription-only medicines.

When using Condylox 0.5% solution together with food and beverages During treatment, alcohol consumption should be avoided. The intake of alcohol during therapy can lead to a massive increase in undesirable effects.

Pregnancy and breastfeeding

Please report the onset of pregnancy to your doctor immediately.

Condylox 0.5% solution causes serious harm to the unborn child if used during pregnancy.

Condylox 0.5% solution must not be used during pregnancy and breastfeeding.

Ability to drive and use machines

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

3. HOW TO USE CONDYLOX 0.5% SOLUTION?

Always use Condylox 0.5% solution exactly as prescribed by your doctor. Please ask your doctor or pharmacist if you are not completely sure.

Condylox 0.5% solution is for the external treatment of genital warts.

The treatment with Condylox 0.5% solution can be carried out at home by yourself.

Only in cases of exceptionally large spread of genital warts (> 4cm²), when the single dose exceeds 0.5ml, should the treatment be carried out by medical personnel.

Before applying the solution, wash the affected areas of the body thoroughly with water and soap and then gently dry them.

Apply the solution to the genital warts with a cotton swab. The cotton swab should only use only once!

Ensure that the solution does not come into contact with the surrounding skin or mucous membranes.

Do not apply Condylor 0.5% solution to other warts.
Allow the solution to dry for a few minutes after application.
Condylor 0.5% solution does not need to be washed off.
Thoroughly clean your hands after each treatment.
Condylor 0.5% solution must not be used in children under 12 years of age.

How often and for how long should you use Condylor 0.5% solution?
Unless otherwise prescribed by a doctor, please adhere exactly to the dosage.

Treatment with Condylor 0.5% solution is carried out twice daily (12 hours apart) for 3 consecutive days.
Afterwards, a treatment-free period of 4 days should be observed.
Treatment with Condylor 0.5% solution should be repeated until the genital warts disappear, with a maximum treatment duration of 4 weeks.
If no treatment success is observed after 4 weeks, please consult your treating physician immediately.

If you have used more Condylor 0.5% solution than you should
The risk of adverse effects is increased with extensive treatment using excessive amounts over a prolonged period or when treating bleeding or recently removed genital warts or in case of accidental application on intact skin or mucous membrane.
In case of overdose, the skin should be thoroughly cleaned with soap and water. Eyes should be thoroughly rinsed with water.

If you forget to use Condylor 0.5% solution
Do not apply a double dose if you have forgotten the previous application.

4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, Condylor 0.5% solution can have side effects, but not everyone will experience them.
Local irritation affects 35-40% of patients and is usually mild to moderate. Only a few patients experience more severe symptoms.

Known side effects

Very common (affects more than 10 out of 100 treated): local irritation of the treated mucous membrane such as itching, burning, pain, redness, ulceration, loss of the outer mucous membrane layer.

Rare side effects, frequency unknown: adhesions and inflammation of the glans and foreskin.

Reporting of side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

Federal Office for Safety in Health Care
Traisengasse 5

A-1200 Vienna
Fax: + 43 (0) 50 555 36207
Website: <http://www.basg.gv.at/>

5. HOW TO STORE CONDYLOX 0.5% SOLUTION?

Do not store above 25°C. Keep in the original package to protect the contents from light.

Keep medicines out of the reach of children.

Do not use the medicine after the expiry date stated on the packaging. The expiry date refers to the last day of the month.

After first opening, Condylox 0.5% solution is stable for 6 weeks.

6. FURTHER INFORMATION

What Condylox 0.5% solution contains

- The active substance is: Podophyllotoxin. 1 ml solution contains 5 mg podophyllotoxin.
- The other ingredients are: lactic acid, sodium lactate, and ethyl alcohol.

What Condylox 0.5% solution looks like and contents of the package

Brown glass bottle with child-resistant screw cap made of polypropylene contains 3.5 ml solution.

Pharmaceutical entrepreneur and manufacturer

Takeda Austria GmbH

St.-Peter-Straße 25

4020 Linz

Austria

Distribution:

G.L. Pharma GmbH, Lannach

Reg. No.: 1-18963

This package leaflet was last approved in February 2014.