

Leaflet

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Patient Information Leaflet



Condyline 0.5% w/v Cutaneous Solution Podophyllotoxin

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.
- In this leaflet, Condyline 0.5% w/v Cutaneous Solution will be called Condyline.

In this leaflet:

1. What Condyline is and what it is used for
2. Before you use Condyline
3. How to use Condyline
4. Possible side effects
5. How to store Condyline
6. Further information

1. What Condyline is and what it is used for

Condyline is an alcoholic solution which contains the active ingredient podophyllotoxin. This is a plant extract which is used to treat small clusters of genital warts in adults known as condylomata acuminata that are found on the penis or on the external female genital organs.

2. Before you use Condyline

Do not use Condyline

- If you are allergic to podophyllotoxin or any of the other ingredients in the medicine (*listed in section 6 'Further Information'*)
- If you are pregnant or breast feeding
- If you are a child under 12 years of age
- On healthy skin, skin that is bleeding or inflamed, or on open wounds after an operation
- In combination with other products containing podophyllin.

Take special care with Condyline

- If you are female, this medicine should only be used under close medical supervision.
- If you are male and have a lot of warts covering an area larger than 4x4 cm. You should only use this medicine under close medical supervision.
- This medicine can cause systemic toxicity (effects on the whole body). The risk of this is increased:
 - by treating mucus membranes or skin that is either normal, thin and fragile, bleeding or had warts recently removed.
 - by treating large areas with excessive amounts for a long time.
 - if other products containing podophyllin are used at the same time as these also contain podophyllotoxin.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Condyline is not recommended for use in women who are pregnant or breast-feeding.

Driving and using machines

This medicine is not expected to interfere with your ability to drive or use machines.

Important information about some of the ingredients of Condyline

This medicinal product contains alcohol (765.74 mg/ml).

3. How to use Condyline

Always use this medicine exactly as your doctor has told you.

Condyline is not recommended for use in children under 12 years of age.

Adults & elderly

First treatment:

1. Start the treatment in the morning.
2. Before applying Condyline, wash the affected parts with soap and water and dry well.
3. Dip the end of the plastic applicator stick, which has a hole in it, into the bottle, enough for the hole to be filled with solution.
4. Apply this solution onto a wart and let it dry by itself. Cover all of your warts with solution in the same way, ensuring that you **do not use more than 50 "dips"**. (Only a small area or small number of warts should be treated at any one time).
5. Firmly replace the top on the bottle and wash your hands.
6. Steps 1-5 should be repeated 12 hours later on the same day, and then twice a day (once in the morning and once in the evening) for the next 2 days so that you **have 6 treatments in 3 days. No more treatments should be used in the first week.**



Extended treatment period:

If your warts have not disappeared or improved after the one week treatment, your doctor may advise you to repeat the series of 6 treatments in 3 days for a second time (starting on the same day of the week as when you first used Condyline). If necessary, this treatment programme may need to be repeated for a third, fourth and fifth week.

If the solution gets into your eyes, immediately bathe them with water or with an appropriate eye cleaning solution if available. Do not keep bathing the eyes as this may cause irritation. In any case, inform your doctor straight away.

If you use more Condyline than you should

If you accidentally apply too much medicine or get it in the wrong place, wash the affected area well with soap and water. There is a risk of systemic toxicity if you use excessive amounts of Condyline for a long time. If you have done this, you should tell your doctor. If someone happens to drink the solution, contact their doctor or nearest Accident & Emergency Department immediately.

If you forget to use Condyline

If you miss a treatment, apply it as soon as you remember. If it is nearly time for your next application, skip the missed dose and continue using Condyline as your doctor has directed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Condyline can cause side effects, although not everybody gets them.

Side effects of Condyline are:

- Inflammation of the foreskin and head of the penis
- Local irritation of the vagina
- Mild irritation of your warts shortly after applying the solution. This may include itching, burning, pain, redness or ulcers on the skin
- Although it is unlikely, some people may experience an allergic reaction to the active ingredient podophyllotoxin - this may be severe and painful redness or irritation, or any other unexpected pain.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Condyline

Keep out of the reach and sight of children.

The product should be stored at room temperature (25 °C), away from naked flames.

Do not use Condyline after 6 weeks from the date you first opened the bottle. Observe the expiry date which is printed on the carton and bottle. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Condyline contains

The **active substance** is: podophyllotoxin 0.5% w/v.

The **other substances** are: lactic acid, sodium lactate and alcohol (96%). (See Section 2 'Important information about some of the ingredients of Condyline').

What Condyline looks like and contents of the pack

Each 5ml pack of Condyline contains 3.5 ml of clear, colourless solution in a glass bottle fitted with a child resistant closure, as well as a supply of special plastic applicator sticks.

Marketing Authorisation Holder

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