

Package leaflet: Information for the patient

Condyline 5 mg/ml Cutaneous Solution Podophyllotoxin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Condyline 5 mg/ml Cutaneous Solution will be called Condyline.

What is in this leaflet:

1. What Condyline is and what it is used for
2. What you need to know before you use Condyline
3. How to use Condyline
4. Possible side effects
5. How to store Condyline
6. Contents of the pack and other 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. What you need to know before you use Condyline

Do not use Condyline

- if you are allergic to podophyllotoxin or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions

Talk to your doctor before taking 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 4 cm² (approximately the size of a postage stamp). You should only use this medicine under close medical supervision.
- This medicine can cause systemic toxicity (side effects that can affect 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.

Other medicines and Condyline

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

Pregnancy and breast-feeding

Do not use Condyline if you are pregnant, trying to become pregnant or breast-feeding. Contraception is recommended while using Condyline if you are of childbearing age.

Driving and using machines

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

Condyline contains alcohol.

This medicinal product contains alcohol (765.74 mg/ml). It may cause burning sensation on damaged skin.

3. How to use Condyline

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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 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 include:

Not known (frequency cannot be estimated from the available data)

- Inflammation of the foreskin and head of the penis
- Local irritation of the vagina
- Irritation of your warts shortly after applying the solution. This may include itching, burning, pain, redness or lesions (abnormal growths) 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.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Condyline

Keep this medicine out of the sight and reach of children.

The product should be stored below 25°C, away from naked flames.

Do not use Condyline after 6 weeks from the date you first opened the bottle.

Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Condyline contains

- The **active substance** is: podophyllotoxin 5 mg/ml.
- The **other substances** are: lactic acid, sodium lactate and alcohol (96%).

(See Section 2 'Condyline contains alcohol'.)

What Condyline looks like and contents of the pack

Each 5ml pack of Condyline contains 3.5ml 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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