Consumer Medicine Information

CONDYLINE[®]

0.5% (5mg/mL) Podophyllotoxin Topical Solution

What is in this leaflet

This leaflet answers some common questions about Condyline[®] solution. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the expected benefits.

Use Condyline[®] as instructed. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What Condyline[®] is used for

Condyline[®] contains a solution of podophyllotoxin, a plant extract, which is used to treat anogenital warts (warts around the anus, on the penis in males, or outside the vagina in females) in adults.

This medicine works by stopping the warts growing and causing the warts to shrivel.

This medicine belongs to a group of medicines which stops cells dividing. It is for EXTERNAL USE only. It must not be swallowed.

Your doctor may have prescribed Condyline[®] for another reason. Ask your doctor why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Condyline[®]

When you must not use Condyline®

Do not use this medicine if you:

- are pregnant or breastfeeding
- are currently using other preparations containing podophyllotoxin
- have an allergy to any medicine containing podophyllotoxin
- have an allergy to any of the other ingredients listed at the end of this leaflet (see **Product Description).** Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Condyline® to treat children.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use Condyline®

Tell your doctor if:

- you are pregnant or plan to become pregnant or are breastfeeding
- you have a known allergy to Condyline[®] or any ingredient listed at the end of this leaflet.
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

Avoid contact of this medicine on healthy skin. Before using Condyline[®] solution, apply a protective layer of a neutral cream, vaseline or zinc ointment on the healthy skin surrounding the warts.

DO NOT let Condyline[®] come into contact with the eyes. It will cause severe irritation. If contact with the eyes happens, rinse the eyes immediately with water; continue rinsing for a long time, and seek medical help.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Condyline[®].

These medicines may be affected by Condyline[®] or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Condyline[®]

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the information on the box, ask your doctor or pharmacist for help.

Before you begin using Condyline®

Before applying Condyline®, wash the affected parts with soap and water and dry well.

How to use Condyline®

Condyline[®] should be applied twice each day for 3 days, one after another, as set out below:

Remember to replace the top firmly on the bottle after each use.

WEEK ONE

<u>Day 1</u>

- Dip the end of the plastic stick applicator with the hole in it (supplied in the box) into the Condyline[®] solution. Just fill the hole with the liquid Condyline[®].
- Take care not to put the solution on healthy skin (see advice above about protecting healthy skin). If you accidentally put on too much or get it in the wrong place, wash well with soap and water.
- Carefully put the liquid Condyline[®] directly on to a wart. Continue doing this until you have covered all the warts with the solution. Do not use more than 50 'dips'.
- Let the Condyline[®] solution dry completely by itself. Wash your hands.

All of these steps together are "<u>one treatment</u>." Repeat "the treatment" about 12 hours later on the same day.

<u>Day 2</u>

Apply two more treatments (12 hours apart), as described for Day 1 treatment.

<u>Day 3</u>

Apply two more treatments (12 hours apart), as described for Day 1 treatment.

This makes a total of six treatments in three days. This is the full course of your treatments for **Week ONE.**

Your doctor may have arranged to see you again after the first week's treatment.

If the warts are not completely better at this time, repeat the full course of six treatments on three consecutive days for a **second week**.

Start on the same day of the week as when you used Condyline® for the first week.

If necessary, you can repeat this course of six treatments on three consecutive days for a third, fourth or up to a fifth week.

Do not use Condyline[®] for more than five consecutive weeks.

How long to use Condyline[®]

Follow carefully all directions given to you by your doctor and the pharmacist. These directions may differ from the information contained in this leaflet.

Do not use this medicine for longer than your doctor tells you. If you use this medicine for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are unsure how long to use Condyline[®], ask your doctor or pharmacist for help.

If you forget to use Condyline®

If it is almost time for your next treatment, skip the treatment you missed and continue with the next treatment when you are meant to. Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double treatment to make up for the treatment that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

While you are using Condyline[®]

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using this medicine.

If you feel that this medicine is not helping your condition, tell your doctor.

Tell your doctor if, for any reason, you have not used this medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Avoid sexual intercourse during treatment. If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not use this medicine if you have a lot of warts, unless your doctor tells you. Do not use on wounds following surgical procedures, or on burns.

Do not use this medicine to treat warts other than genital warts, moles or other skin conditions.

Do not use this medicine in or near the eyes.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they appear to have the same condition as you.

Things to be careful of

Do not use large amounts of this medicine for a long time. If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increases.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using this medicine.

Side-Effects

Like all medicines, Condyline[®] can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Tell your doctor or pharmacist if you have any unpleasant effects while you are using Condyline[®] even if you do not think the effect is connected with the medicine or is not listed in this leaflet.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

You should expect some irritation of the warts soon after you use Condyline[®], due to its

action. Redness with discomfort and/or superficial ulceration in the treated area is to be expected. Further applications of Condyline[®] may sting and be rather painful. Tell your doctor as soon as possible if you experience any of the following:

- severe burning, itching or irritation of the skin at the site of contact with the medicine
- severe and painful redness of the skin or rash
- swelling or build-up of fluid in the genital area

The above list includes serious side effects, usually caused by continued use on large areas of skin, which may require medical attention. (Serious side effects are rare.)

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

In case of Overdose

If you swallow Condyline[®]

Immediately telephone your doctor or the Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

After using Condyline[®]

Keep Condyline[®] in pack until required.

Storage

Store Condyline[®] in a cool dry place where the temperature stays below 25 °C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep Condyline[®] where children cannot reach it. A locked cupboard at least one-and-a- half metres above the ground is a good place to store medicines.

Do not use Condyline[®] after the expiry date on the package or six weeks after first opening the bottle.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Condyline[®] looks like

Condyline[®] is a clear, colourless solution with a smell of alcohol.

Ingredients

Active Ingredient:

Condyline® contains 5 mg/mL podophyllotoxin as the active ingredient.

Inactive Ingredients:

- lactic acid
- sodium lactate
- alcohol
- purified water

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This is not all the information available on Condyline[®]. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

Condyline® is supplied in New Zealand by:

AFT Pharmaceuticals Ltd Level 1, 129 Hurstmere Road, Takapuna Auckland Free phone: 0800 423 823 E-mail: cutomer.service@aftpharm.com

This leaflet was prepared in March 2017.