

# Podophyllotoxin 0.5% w/v Cutaneous Solution

**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.

## What is in this leaflet:

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

## 1. What Podophyllotoxin Cutaneous Solution is and what it is used for

Podophyllotoxin Cutaneous Solution contains a medicine called podophyllotoxin. This is a plant extract which belongs to a group of medicines called 'antivirals'.

Podophyllotoxin Cutaneous Solution is used to treat genital warts. It is used for warts on the foreskin of the penis in men or external warts on the vagina in females.

## 2. What you need to know before you use Podophyllotoxin Cutaneous Solution

### Do not use Podophyllotoxin Cutaneous Solution if:

- you are allergic to podophyllotoxin or any of the other ingredients of this medicine (listed in Section 6)
- your warts are on areas of broken/damaged or bleeding skin
- you are already using another medicine containing podophyllotoxin.

Do not use Podophyllotoxin Cutaneous Solution if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using this medicine.

### Warnings and precautions

Talk to your doctor before using this Podophyllotoxin Cutaneous Solution if:

- your warts cover an area larger than a 4 centimetre area (approximately the size of a postage stamp). You may need to have this medicine applied by your doctor or nurse in a clinic.

**Podophyllotoxin Cutaneous Solution is only to be used on the affected skin.** Don't take Podophyllotoxin Cutaneous Solution by mouth.

**Don't apply Podophyllotoxin Cutaneous Solution to warts on the inside of the penis, vagina or rectum.** Podophyllotoxin Cutaneous Solution should only be applied to warts on the outside (external) skin.

**Avoid applying Podophyllotoxin Cutaneous Solution to healthy skin** surrounding the wart.

**Avoid getting Podophyllotoxin Cutaneous Solution in your eyes** as it may cause irritation. **If you accidentally get Podophyllotoxin Cutaneous Solution in your eyes** rinse immediately with plenty of water and see a doctor.

**Don't put a dressing (such as a plaster)** over the top of the area treated with Podophyllotoxin Cutaneous Solution.

→ **Check with your doctor** if you think any of these may apply to you.

## What to avoid while using Podophyllotoxin Cutaneous Solution

- It is advisable to **avoid sex** during treatment with Podophyllotoxin Cutaneous Solution. You should wait until your warts have gone and your skin has healed
- **Genital warts are contagious.** You can give them to, or get them from, a sexual partner.

→ If you do have sex, you must use a condom to help prevent the spread of genital warts and to protect your partner from coming into contact with podophyllotoxin (since it is irritant).

## Other medicines and Podophyllotoxin Cutaneous Solution

**Tell your doctor or pharmacist if you are taking any other medicines**, if you have taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

## Children

The use of Podophyllotoxin Cutaneous Solution is not recommended for children under 18 as use in this age has not been established.

## Pregnancy and breast-feeding

**Podophyllotoxin Cutaneous Solution is not recommended for use during pregnancy.**

- **Tell your doctor if you are pregnant** or planning to become pregnant
- **Use a reliable method of contraception** to prevent pregnancy, while you are using Podophyllotoxin Cutaneous Solution
- **If you do become pregnant during treatment** with Podophyllotoxin Cutaneous Solution, tell your doctor.

**Breast-feeding is not recommended** during treatment with Podophyllotoxin Cutaneous Solution. Discuss with your doctor whether you choose to breast-feed or to use podophyllotoxin.

## 3. How to use Podophyllotoxin Cutaneous Solution

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Use this medicine only on your skin.

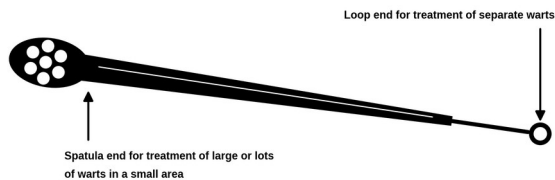
### How much to use

- Apply Podophyllotoxin Cutaneous Solution twice a day, in the morning and evening (every 12 hours) for 3 days.
- Do not apply any Podophyllotoxin Cutaneous Solution for the next 4 days. This completes one treatment course.
- When you apply Podophyllotoxin Cutaneous Solution, after two or three days you may notice mild irritation of the areas treated. This shows that Podophyllotoxin Cutaneous Solution is starting to work. However, Podophyllotoxin Cutaneous Solution can cause severe **skin reactions**. If this occurs, stop using Podophyllotoxin Cutaneous Solution and seek medical attention. See 'Possible side effects' in **Section 4** for further information. If you still have any warts remaining 7 days after you have started using Podophyllotoxin Cutaneous Solution, repeat the treatment course (twice a day for 3 days followed by 4 days when you do not apply it).
- A maximum of 4 treatment courses may be applied.
- If any warts remain after 4 treatment courses, see your doctor.
- Due to the flammable nature of Podophyllotoxin Cutaneous Solution, you should avoid smoking or being near an open flame while you're applying Podophyllotoxin Cutaneous Solution, and immediately after you've used it.

### How to apply Podophyllotoxin Cutaneous Solution

1. Wash the affected areas with soap and water. Dry the area gently with a clean towel.

2. Use a new applicator each time you apply Podophyllotoxin Cutaneous Solution.
3. Dip the 'Loop' end of the applicator into the Podophyllotoxin Cutaneous Solution. If you have a large wart (no larger than a postage stamp) or lots of warts in a small area, dip the 'Spatula' end of the applicator into the solution.
4. Apply the solution to a wart until it is just covered and allow to dry. Be careful not to get the Podophyllotoxin Cutaneous Solution onto healthy skin. If this happens, wash the solution off with soap and water.
5. Repeat steps 3 and 4 for each wart. Allow all the skin treated with Podophyllotoxin Cutaneous Solution to dry before letting other skin touch the affected area.
6. Wash your hands thoroughly after using Podophyllotoxin Cutaneous Solution.
7. Make sure you screw the lid back on tightly.



#### If you get Podophyllotoxin Cutaneous Solution in your eyes or if you swallow it

- If you get Podophyllotoxin Cutaneous Solution in your eye, rinse the eye thoroughly with water and see your doctor.
- If you accidentally get Podophyllotoxin Cutaneous Solution in your mouth, rinse at once with water.
- If you accidentally swallow some of the Podophyllotoxin Cutaneous Solution, see your doctor or go to hospital straight away. Take the bottle of Podophyllotoxin Cutaneous Solution with you so that the doctor knows what you have swallowed.

#### If you use too much Podophyllotoxin Cutaneous Solution

If you accidentally use too much solution, wash it from the treatment area immediately and see a doctor.

#### If you forget to use Podophyllotoxin Cutaneous Solution

Apply Podophyllotoxin Cutaneous Solution as soon as you remember. If it is nearly time for your next dose, wait until then.

**Don't use a double dose** of the medication.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody will get them.

If you experience any of the following serious side effects, stop using Podophyllotoxin Cutaneous Solution and seek emergency medical attention:

- severe burning, stinging, pain, bleeding, itching or swelling of the treated skin. If these symptoms occur, wash Podophyllotoxin Cutaneous Solution from your skin with soap and water immediately.

→ **Contact your doctor immediately.**

#### Very common side effects

These may affect **more than 1 in 10 people**:

- wearing away of the top layers of the skin, application site irritation including redness, itching, burning sensation

Other side effects with frequencies that cannot be estimated from the available data include:

- allergic reaction, pain, swelling, bleeding

- damage to or loss of the top layer of skin, weeping wound
- skin ulcer, scab, skin discoloration, dry skin, blister.

These effects can occur on the area of skin where you use the solution.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Podophyllotoxin Cutaneous Solution

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Store Podophyllotoxin Cutaneous Solution at room temperature (below 25°C). Keep the container tightly closed when not in use.
- Contents are flammable. Keep Podophyllotoxin Cutaneous Solution away from all sources of fire, flame and heat.
- Do not leave Podophyllotoxin Cutaneous Solution in direct sunlight.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

#### What Podophyllotoxin Cutaneous Solution contains

- The active ingredient is podophyllotoxin 0.5% w/v.
- The other ingredients are phosphoric acid, ethanol, Patent Blue V (E131) and purified water.

#### What Podophyllotoxin Cutaneous Solution looks like and contents of the pack

Each pack of Podophyllotoxin Cutaneous Solution contains a bottle of Podophyllotoxin Cutaneous Solution and a tub of double-ended applicators.

#### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Phoenix Labs  
Suite 12, Bunkilla Plaza,  
Bracetown Business Park,  
Clonee, County Meath, Ireland

Manufacturer:

Delpharm Bladel B.V.  
Industrieweg 1,5531 AD Bladel, The Netherlands

#### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please contact:

Phoenix Labs  
Suite 12, Bunkilla Plaza,  
Bracetown Business Park,  
Clonee, County Meath, Ireland

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