## Wartec Solution®

0.5% w/v podophyllotoxin

#### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about Wartec Solution. It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have benefits and risks. Your doctor has weighed the benefits of you using Wartec Solution against the risks they expect it may have for you.

If you have any concerns about this medicine, ask your doctor.

### Keep this leaflet with your medicine.

You may need to read it again.

# What Wartec Solution is used for

Wartec Solution contains podophyllotoxin, a plant extract that has antiwart properties. It works by destroying the skin of the wart.

Wartec Solution is used on the skin to treat warts that are found in the external genital region (penis or vulva) or around the anus.

It should not be used to treat warts that are found inside the anus or urinary canals of the penis or the vulva.

These types of warts are commonly referred to as anogenital or venereal warts.

They are caused by the Human Papilloma Virus (HPV). Up to half of sexually active adults are infected with HPV but only a small percentage will show outward signs of the virus.

Anogenital warts are usually soft and skin coloured with a fleshy appearance.

They are contagious and infection can occur through direct skin-to-skin contact. In adults, infection commonly occurs through sexual contact.

Anogenital warts generally appear about 3 months after infection occurs; however they may not show themselves for over a year.

Wartec Solution is not addictive.

Wartec Solution is only available with a doctor's prescription.

# Before you use Wartec Solution

When you must not take it

### Do not use Wartec Solution if you have an allergy to:

- any medicine containing podophyllotoxin
- any of the ingredients listed at the end of this leaflet.

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

 add any other specific reactions listed in the PI.

Do not use Wartec Solution on friable or bleeding warts.

Do not use Wartec Solution on open wounds e.g. after surgical procedures, such as biopsies, to the anogenital region.

### Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breast-feed if you are using this medicine.

Do not give this medicine to a child under the age of 12 years.

Do not take 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.

If you are not sure whether you should start using Wartec Solution, contact your doctor.

#### Before you start to use it

- Podophyllotoxin should not be used on cervical or urethral warts.
- All women with genital warts should have Pap smears because of the association between human papilloma infection and carcinoma of the cervix. This is also recommended for female partners of males with genital warts.
- Tell your doctor if:
- you have any type of allergic reaction to podophyllotoxin or any other ingredient listed at the end of this leaflet.

- you are pregnant or intend to become pregnant.
- you are breast-feeding or intend to breast-feed.
- you have had or have any other medical conditions.

If you have not told your doctor about any of the above, tell him before you use Wartec Solution.

### Using other medicines

Tell your doctor if you are using other creams, ointments or lotions or taking any other medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Your doctor may have more information on medicines to be careful with or avoid while using Wartec Solution.

# How to use Wartec Solution

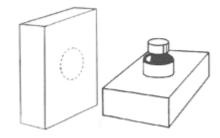
Due to the flammable nature of Wartec Solution, you should avoid smoking or immediately after you've used it.

### For use under medical supervision only. Follow all directions given to you by your doctor carefully.

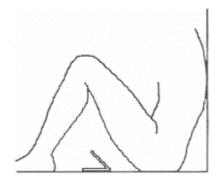
These directions may differ from the information contained in this leaflet.

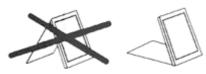
If you do not understand the instructions on the box, tube or this leaflet, ask your doctor for help.

- Before applying the solution, wash the affected areas with soap and water and dry thoroughly with your own towel.
- 2. To assist you in applying the solution, push in the perforated circle on the large face of the carton and place the bottle inside as shown in the diagrams below.



It may help you to view the area to be treated if you sit down and place the mirror as shown in the diagrams.





#### Incorrect

Correct

- 4. Each applicator has a single 'loop' on one end with multiple perforations on the other. The single 'loop' is used for small warts. The end with perforations is used for larger warts.
- 5. Using one of the applicators, dip the appropriate end into Wartec Solution and continue to apply until the wart is just covered with the solution. You will not normally require more than 30 'loops' in any one application.



6. Repeats Steps 4 and 5 if you have more than one wart and allow the solution to dry.

Apply Wartec Solution twice daily, morning and evening (every 12 hours), for 3 days only, followed by 4 days without treatment (one treatment course).

### Never reuse an applicator or dip a used applicator in the bottle.

If you have any warts remaining 7 days after you started using the solution, repeat the treatment course (twice a day for 3 days followed by 4 treatment-free days).

Day	Morning	Evening
	-	
1	W	W
2	W	W
3	W	W
4		
5	Treatment Free days	
6		
7		
8	W	W
9	W	W
10	W	W
11		
12		
13	Treatment Free days	
14		
15	W	W
16	W	W
17	W	W
18		
19		
20	Treatment Free days	
21		
22	W	W
23	W	W
24	W	W

### It is important to use Wartec Solution exactly as your doctor has told you.

If you use it less often than you should, it may not resolve your warts. Using it more often than you should may not resolve your warts any faster and may cause or increase side effects.

How long should you use it for

# You should use Wartec Solution for as long as your doctor tells you to.

If you use Wartec Solution for longer than your doctor tells you, the chance of side effects may increase.

Generally a maximum of 4 treatment courses (maximum of 24 applications) may be applied.

If any warts remain after 4 treatment courses consult your doctor.

If you are not sure of how long you need to use Wartec Solution, talk to your doctor.

If you forget to use it

If it is almost time for your next application of Wartec Solution, skip the application you missed and apply the solution when you are next meant to. Otherwise, use it as soon as you remember, and then go back to using your solution as you would normally.

### Do not use a double dose to make up for the dose that you missed.

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

If you swallow it

Immediately telephone your doctor, local hospital or Poisons Information Centre (Phone 13 11 26) if you think that you, or anyone else may have swallowed Wartec Solution. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep this telephone number handy.

# While you are using Wartec Solution

Things you must do

Tell your doctor(s) who is treating you that you are using Wartec Solution.

If you feel that Wartec Solution is not helping your condition or if it becomes worse, tell your doctor.

### Tell your doctor if for any reason, you have not used Wartec Solution exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using Wartec Solution, tell your doctor.

### Avoid sexual intercourse during treatment.

The use of a condom is no guarantee that anogenital warts will not be transferred to another person.

### Avoid contact of Wartec Solution with your eyes.

If you accidentally get Wartec Solution in your eye, rinse the eye thoroughly with water and consult your doctor.

Things you must not do

### Do not apply Wartec Solution to healthy skin.

If the solution spreads to healthy skin it should be washed off with soap and water.

Avoid applying Wartec Solution to areas of the genitals such as urethra, rectum and vagina.

Treatment of large areas should take place under the direct supervision of a healthcare professional.

Do not use occlusive (air or water tight) dressings on areas treated with Wartec Solution.

Do not apply Wartec Solution to large areas with excessive amounts for prolonged periods.

Do not give Wartec Solution to anyone else, even if they have the same symptoms as yours.

### Do not use Wartec Solution near heat, an open flame or while smoking.

Wartec Solution contains alcohol and may be flammable.

### Things to be careful of

Be careful driving or operating machinery until you know how Wartec affects you. Wartec does not cause any problems with your ability to drive a car or operate machinery. However, it may cause local irritation on application.

### Side effects

### Tell your doctor if you do not feel well while you are using Wartec Solution.

Wartec Solution helps most people with anogenital warts but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following near or on the area you apply Wartec Solution and they worry you:

- irritation
- itching
- tenderness
- smarting

These may occur on the second or third day of treatment as the warts begin to disappear. In most cases these effects are mild and will pass.

If itching or soreness persist and cause severe discomfort, wash treatment area with mild soap and water, stop the treatment and seek medical advice.

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

Ask your doctor if you don't understand anything in the above list.

# After using Wartec Solution

### Storage

Keep Wartec Solution in a cool dry place where the temperature stays below 25°C.

### Keep the cap tightly closed when you are not using Wartec Solution.

Contents are flammable. Keep Wartec Solution away from all sources of fire, flame and heat. Do not leave Wartec Solution in direct sunlight.

Do not store Wartec Solution or any other medicine in the bathroom or near a sink.

### Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not refrigerate Wartec Solution.

### Keep Wartec Solution where young children cannot reach it.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

#### Disposal

If your doctor tells you to stop using Wartec Solution or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

### Product description

#### What it looks like

Wartec Solution comes in an amber glass bottle containing 3ml of blue solution. A small mirror and a tube of double-ended applicators are provided in each pack to help application.

### Ingredients

The active ingredient in Wartec Solution is podophyllotoxin 0.5%.

Wartec Solution also contains the following inactive ingredients:

- ethanol
- phosphoric acid
- Patent Blue V
- purified water

### Supplier

Wartec Solution is supplied in Australia by:

### GlaxoSmithKline Australia Pty Ltd

Level 4 436 Johnston Street Abbotsford Victoria 3067 Australia

### **Australian Registration Number:**

AUST R 33694

#### Date of preparation:

16 September 2013

Wartec® is a registered trade mark of Stiefel Laboratories Inc.

Version 4.0

