Wartec Cream®

0.15% w/v podophyllotoxin

Consumer Medicine Information

What is in this leaflet

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

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

All medicines have benefits and risks. Your doctor has weighed the benefits of you using Wartec Cream 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 Cream is used for

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

Wartec Cream 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-toskin 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 Cream is not addictive.

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

Before you use Wartec Cream

Do not use Wartec Cream 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 Cream if you are currently using other preparations containing podophyllotoxin.

Do not use Wartec Cream on friable or bleeding warts.

Do not use Wartec Cream 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 Cream, 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 Cream.

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 Cream.

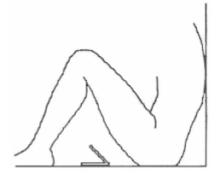
How to use Wartec Cream

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 cream, wash the affected areas with soap and water and dry thoroughly with your own towel.
- 2. 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

 Using a finger apply enough cream to just cover each wart.
The cream should be gently rubbed in.

Wash your hands as soon as you finish using Wartec Cream.

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

If you have any warts remaining 7 days after you started using the cream, 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 | Treatment Free days | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | W | W |
| 9 | W | W |
| 10 | W | W |
| 11 | Treatment Free days | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | W | W |
| 16 | W | W |
| 17 | W | W |
| 18 | Treatment Free days | |
| 19 | | |
| 20 | | |
| 21 | | |
| 22 | W | W |
| 23 | W | W |
| 24 | W | W |

It is important to use Wartec Cream 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 Cream for as long as your doctor tells you to.

If you use Wartec Cream 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 Cream, talk to your doctor.

If you forget to use it

If it is almost time for your next application of Wartec Cream, skip the application you missed and apply the cream when you are next meant to. Otherwise, use it as soon as you remember, and then go back to using your cream 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 for Australia or 0800 POISON or 0800 764 766 for New Zealand) if you think that you, or anyone else may have swallowed Wartec Cream. 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 Cream

Things you must do

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

If you feel that Wartec Cream 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 Cream 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 Cream, 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.

If a condom is to be used the cream should be washed off before use. The cream should not be washed off until at least one hour after application.

Avoid contact of Wartec Cream with your eyes.

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

Things you must not do

Do not apply Wartec Cream to healthy skin.

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

Avoid applying Wartec Cream 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 Cream.

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

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

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 Cream.

Wartec Cream 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 Cream and they worry you:

- irritation
- · itching
- · tenderness
- smarting

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 Cream

Storage

Keep Wartec Cream in a cool dry place where the temperature stays below 30°C.

Do not store Wartec Cream 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 Cream.

Keep Wartec Cream where young children cannot reach it.

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

Disposal

If your doctor tells you to stop using Wartec Cream 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 Cream comes in a single tube containing 5g of white cream. A small mirror is provided in each pack to help application.

Ingredients

The active ingredient in Wartec Cream is podophyllotoxin 0.15%.

Wartec Cream also contains the following inactive ingredients:

- purified water
- methyl hydroxybenzoate
- · propyl hydroxybenzoate
- sorbic acid
- phosphoric acid
- stearyl alcohol
- steareth-7
- steareth-10
- cetyl alcohol

- · isopropyl myristate
- liquid paraffin
- medium chain triglycerides
- butylated hydroxyanisole (BHA)

Supplier

Wartec Cream is supplied in

Australia by:

GlaxoSmithKline Australia Pty Ltd

Level 4

436 Johnston Street

Abbotsford

Victoria 3067

Australia

Wartec Cream is supplied in New

Zealand by:

GlaxoSmithKline NZ Limited

Private Bag 106600

Downtown

Auckland 1143

New Zealand

Australian Registration Number:

AUST R 78993

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