

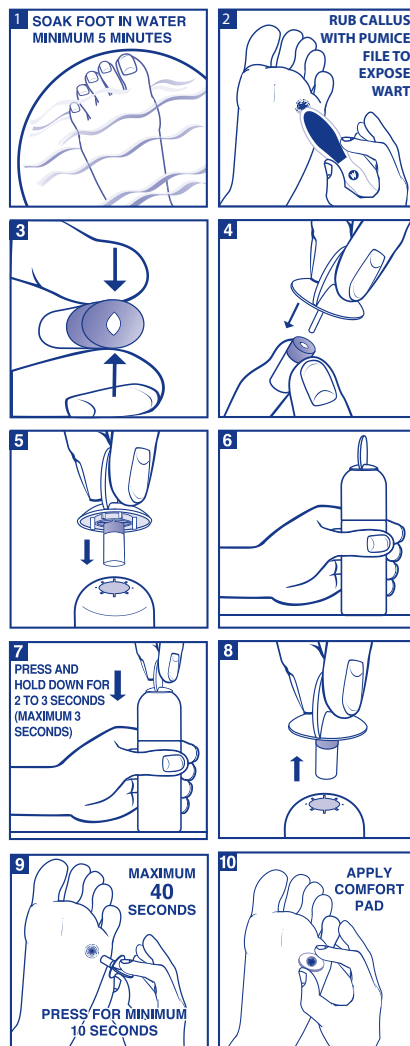
WARTNER®

WART REMOVAL SYSTEM

READ THIS ENTIRE INFORMATION LEAFLET CAREFULLY BEFORE USE. KEEP FOR REFERENCE.

I. Instructions for Use (Plantar Warts)

1. Soak foot with the plantar wart in warm water for 5 minutes. Dry thoroughly.
2. File the plantar wart area with file supplied, prior to treatment.
3. Squeeze the coloured end of the **foam applicator** between the thumb and index finger until a small opening appears.
4. Slide the opening on the coloured end of the **foam applicator** over the stick of the **applicator holder** until the stick is no longer visible. You will find the **applicator holder** in the bag containing the **foam applicators**.
5. Insert the **applicator holder** with the attached **foam applicator** into the opening on the top of the **aerosol can** so that the **foam applicator** is no longer visible.
6. Place the **aerosol can** firmly on a table or other sturdy surface. **Caution!** Do not hold the spray can near your face, or over parts of your body or clothing, and or near ignition source.
7. Holding the **aerosol can** firmly with one hand (see picture 7), firmly press down on the **applicator holder** with the other hand until you hear a hissing sound. Continue to press down for 2 to 3 seconds. You will hear a hissing sound for the entire period. Do not press for more than 3 seconds.
8. Pull the **applicator holder** with the attached **foam applicator** out of the valve. The white end of the **foam applicator** is saturated with cold liquid and you will see condensation (white frosty appearance). You may smell some dimethyl ether.
9. Leave the **foam applicator** on the **applicator holder** and, grasping the **applicator holder**, lightly press the white tip of the **foam applicator** for several seconds on the wart that is to be frozen. Do not swab. Wartner® should be applied immediately. Hold the **foam applicator** on plantar warts on areas with thicker or calloused skin, such as the balls of the foot or heel, for 40 seconds or less. Treat plantar warts occurring on less calloused areas of the foot, such as the arch of the foot or toes, for 20 seconds or less (see Figure 1). There will be an aching, itching, stinging sensation. Wait 2 minutes before using a tissue to remove the **foam applicator** from the holder. Discard the **foam applicator** after single use. Do not reuse **foam applicator** or touch the white end of the **foam applicator** with bare hands to ensure that reinfection with the wart virus does not occur.
10. Comfort pads have been included with the Wartner® Plantar Kit only. This can be used to protect the tender plantar wart area after treatment has been completed. Carefully remove pad from backing. Apply adhesive side of pad to skin with hole directly over the small tender spot.



J. Application Times

After the foam applicator is saturated with the freezing liquid, hold it on the common wart for 20 seconds or less, depending on the size of the wart. If you use it on a plantar wart on an area of the foot with thicker or calloused skin, such as the balls of the foot or the heel, hold the foam applicator on the plantar wart for 40 seconds or less. Treat plantar warts occurring on less calloused areas of the foot, such as the arch of the foot or toes, for 20 seconds or less. Calloused areas of the foot vary from person to person. If the area of the foot where the plantar wart occurs is not calloused, do not apply Wartner® for more than 20 seconds.

K. Follow-up Treatment

- After application, the colour of the skin may change, varying from white to red. A blister may form under the wart and aching/stinging feeling normally will occur for up to a few hours. If the aching, stinging feeling continues until the next day or if another problem, such as freezing the skin beyond the size of the wart or loss of feeling occurs, contact your doctor. It is normal for the treated area to be sensitive for a few days.
- Black dots may appear in the centre of the treated wart after a few days.
- Do not pick or scratch the treated area as this may result in infection.
- Do not puncture blisters. Puncturing blisters will be painful and may result in infection.
- Keep the treated area clean.
- You may swim or shower.
- Protect blisters, if necessary, with a gauze or sterile adhesive bandage.

Manufactured by:
Omega Teknika
Farnham Drive,
Finglas Dublin 11,
Ireland

Distributed by:
Omega Pharma
PO Box 602
Terrey Hills
NSW 2084
Australia

www.omegapharma.com.au

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A. Contents of Wartner® Wart Removal System

All kits- An aerosol spray can with a mixture of dimethyl ether and propane, one reusable applicator holder, this information leaflet in which you can read about the product, how it works, how to use the product to treat warts, and warnings and limitations.

Wartner® - Twelve 7 mm blue disposable foam applicators.

Wartner® Plantar Kit- One file, 12 comfort pads, twelve 8 mm green disposable foam applicators.
One measuring tool.

B. Background on Warts:

Warts are growths on the skin or mucous membranes (such as inside mouth, nose, anus, genitals, lips) that are caused by the human papilloma virus (HPV). There are more than 80 different types of HPV. Many are attracted to the skin where they cause different skin-related warts including plantar warts and common warts. Others are attracted to the mucous membranes where they can cause warts on the genitals or anus. Skin-related warts such as common warts and plantar warts are generally harmless.

Warts are most common in children and adolescents. Warts are very contagious and may appear more often if the body's defence system is weak. Warts are passed from person to person or from one body location to another on the same person by touch or contact with the flakes of skin. More than 50% of warts disappear within two years with no treatment. However, they are unsightly and can cause pain in the case of plantar warts. Therefore, patients often choose to treat warts rather than wait for them to disappear.

Liquid nitrogen is the most commonly applied freezing method, but it is only available through the physician. Wartner® is an alternative to liquid nitrogen. It contains dimethyl ether and propane (DMEP).

C. What is Wartner® Wart Removal System used for?

Wartner® Wart Removal System is used for the removal of common warts as well as the removal of plantar warts on the bottom of the foot. Common warts and plantar warts are harmless growths that consist of a centre of inner skin (or connective) tissue with blood vessels covered with layers of outer skin (or epidermis) tissue. Common warts are skin coloured, usually appear on the hands and feet and are easily recognized by the rough "cauliflower-like" appearance of the surface. Plantar warts only occur on the bottom of the foot and are often flat due to the pressure caused by walking. Plantar warts grow inward, are often calloused, and can be very painful. The footprint pattern is smooth over the area where the plantar wart occurs because "skin lines" do not grow across the surface of plantar warts.

D. Warnings

- Do not use if you cannot see clearly to read the information on the container or the information leaflet. Use only as directed.
- Do not use if you cannot see clearly the wart you are treating. If you mistakenly apply Wartner® directly to skin or use it on conditions that are not warts, it may cause serious burns and permanent scarring of the skin.
- Do not use on children under the age of 4 years. It is uncertain how Wartner® may affect the child's skin. Use on a child under 4 may cause permanent scarring of the child's skin.
- Do not use if you are diabetic or if you have poor blood circulation. Wartner® works by freezing the wart. The frozen area in diabetic patients and those with poor blood circulation may not heal as quickly or completely. Do not use if you are pregnant or breast feeding. It is uncertain how Wartner® may affect patients under these conditions.
- Do not use on areas with thin skin such as the face, armpits, breasts bottom, or genitals. Use on these areas may cause burns and permanent scarring.
- Do not use on irritated skin, or on any area that is infected, reddened or showing any signs of inflammation, such as itching or swelling. Treating these areas with Wartner® will result in worsening of the condition and possible further infection. These conditions may not be warts and should be examined by a Medical Practitioner.

Do not use on moles, birthmarks, warts with hair growing from them, genital (on penis or vaginal area) warts, or warts on the face or mucous membranes (such as inside mouth, nose, anus, genitals, lips, ears or near eyes). Use on these areas may cause burns and permanent scarring of the skin or blindness.

Use Wartner® only if you are sure the skin condition is a wart. If you are not sure, consult your Medical Practitioner. If you treat a skin condition as a wart with Wartner® and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease.

Avoid contact with Eyes. Contact with eyes may cause blindness. Do not rub or touch eyes with hands if Wartner® has been applied to them. If product gets into eyes, flush with water for 15 minutes and get medical help right away.

Do not Swallow. Contents are toxic and may cause serious internal damage. If swallowed, get medical help or contact a Poison Control Centre right away.

For External Use Only. Use only as directed. If Wartner® is not used exactly as instructed or you mistakenly apply it directly to the skin or use it on conditions that are not warts, it may cause serious burns and permanent scarring of the skin.

Keep Out of Reach of Children. Children cannot understand the instructions to properly use this product. Contents are hazardous if swallowed, breathed, sprayed on body parts other than warts, or exposed to heat.

E. Cautions

- The lot number and expiration date appear on the bottom of the **aerosol spray can** as well as the outside of the carton.
- Use Wartner® only in combination with the special disposable **foam applicators** provided in this package. Wartner® may not be effective if used in combination with other applicators, foam or otherwise.
- Use one **foam applicator** for one treatment for each wart; use each **foam applicator** only once. Do not reuse **foam applicator** or touch the white end of the **foam applicator** with bare hands to ensure that you do not spread the wart virus infection.
- If there is more than one wart on a finger or toe, only treat one wart at a time. Freezing more than one wart on a single finger or toe is too large an area to freeze at one time and may take longer to heal or the area may not heal properly. Treat each remaining wart on a single finger or toe separately with a two-week period between treatments.
- In most cases, only one treatment is needed for each wart. Warts are usually gone in two weeks after treatment with Wartner®. If a wart or part of it is still there two weeks after treatment, you may treat it again. Do not treat each wart with Wartner® more than three times in total. Consult your Medical Practitioner if three treatments have not led to improvement.
- The aching/stinging feeling in treated common warts should disappear within a few hours of application. For plantar warts, the aching/stinging feeling may last 24 hours. If discomfort or aching/stinging feeling continues beyond these times, 3 hours for common warts and 24 hours for plantar warts, talk to your Medical Practitioner. This may mean that the area has been frozen too deeply and medical attention may be needed.
- Do not inhale vapour/spray and use only in well ventilated areas because it is uncertain how the vapour/spray will affect the lungs. Breathing vapour/spray may be toxic.
- Wash hands (except treated area) immediately after use. Washing the treated area immediately may be uncomfortable since you may still be experiencing some aching/stinging. The treated area may be washed after the aching/stinging subsides.

Extremely Flammable. Contents under pressure. Do not pierce or burn **aerosol spray can**, even after use. Protect from sunlight and do not expose to temperatures above 50 °C (120 °F). Store at room temperature away from heat. Keep away from fire or flame and from sources of sparks or ignition. Do not smoke while using Wartner®. Piercing the container or exposure to heat may cause the container to explode, causing serious injury. Do not breathe vapour/spray and use only in well ventilated areas because it is uncertain how the vapour/spray will affect the lungs. Breathing vapour/spray may be toxic.

F. What to do if you are uncertain if the condition is a wart?

See "Warnings" and "Cautions". **Use Wartner® only if you are sure the skin condition is a wart.** If you are not sure, consult your Medical Practitioner. If you treat a skin condition as a wart with Wartner® and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease.

G. How does Wartner® work?

- Wartner® freezes warts. The freezing kills both the virus and the infected skin. When the **foam applicator** is pressed on the wart, freezing begins within a few seconds and the skin will turn white (see diagram and instructions for use). A slight aching, itching and/or stinging feeling will occur as a result of the freezing. After the **foam applicator** is removed, colour will return and the aching, itching, stinging feeling will quickly decrease, disappearing within a few hours.

- After the area thaws and colour returns, a redness that is the same size as the frozen region may appear. As a result of freezing, a blister may form (sometimes filled with blood) under the wart within a few days. You may not see this easily.
- The frozen skin with the treated wart will fall off after about 10 - 14 days. In the meantime, new skin will have formed under the blister.

H. Side Effects

- A stinging, itching, aching feeling during and after freezing that quickly decreases after the area thaws.
- Applying foam applicator greater than 20 secs on toes may lead to nerve damage.
- Black dots appear in the middle of the wart after a few days.
- Temporary pigmentation change may occur.
- Possible blistering

I. Instructions for Use (Common Warts)

- Squeeze the coloured end of the **foam applicator** between the thumb and index finger until a small opening appears.
- Slide the opening on the coloured end of the **foam applicator** over the stick of the **applicator holder** until the stick is no longer visible. You will find the applicator holder in the bag containing the **foam applicators**.
- Insert the **applicator holder** with the attached **foam applicator** into the opening on the top of the **aerosol can** so that the **foam applicator** is no longer visible.
- Place the **aerosol can** firmly on a table or other sturdy surface. **Caution!** Do not hold the spray can near your face, or over parts of your body or clothing.
- Holding the **aerosol can** firmly with one hand at the bottom, firmly press down on the **applicator holder** with the other hand until you hear a hissing sound. Continue to press down for 2 to 3 seconds. You will hear a hissing sound for the entire period.
- Pull the **applicator holder** with the attached **foam applicator** out of the valve. The white end of the foam applicator is saturated with cold liquid and you will see condensation (white frosty appearance). You may smell some dimethyl ether.
- Leave the **foam applicator** on the **applicator holder** and, grasping the **applicator holder**, lightly press the white tip of the **foam applicator** for several seconds on the wart that is to be frozen. Do not Swab. Wartner® should be applied immediately. **Hold the foam applicator on common warts for 20 seconds or less.** Smaller warts may require less than 20 seconds. When treating warts on the top of fingers and toes, slowly move the fingers or toes while administering treatment. There will be an aching, itching, stinging sensation. Wait 2 minutes before using a tissue to remove the **foam applicator** from the holder. Discard the **foam applicator** after single use. Do not reuse **foam applicator** or touch the white end of the **foam applicator** with bare hands to ensure that reinfection with the wart virus does not occur.