

**DrScholl's**<sup>®</sup>

# **FREEZE AWAY**<sup>®</sup>

**COMMON & PLANTAR WART REMOVER**

**STOP** READ THE COMPLETE INFORMATION BOOKLET CAREFULLY  
BEFORE EACH TIME YOU USE THIS PRODUCT.

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## **A. Contents of Freeze Away<sup>®</sup> Wart Remover**

1. Pressurized can with a mixture of dimethyl ether and propane that is not harmful to the environment.
2. 12 disposable applicators for 12 applications of Freeze Away.
3. 1 reusable cup.
4. This information booklet in which you can read about the product, how Freeze Away works, how to use the product to treat common warts and plantar warts, and warnings and limitations.

## **B. Background**

- ▶ 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 common warts and plantar warts. Skin-related warts such as common warts and plantar warts are generally harmless.
- ▶ Warts affect 7 to 10% of the general population. They are most common in children and adolescents. Warts are very contagious and may appear more often if the body's defense 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, people often choose to treat warts rather than wait for them to disappear.

- ▶ Treatments for warts include different topical preparations. Surgical removal, burning and cryotherapy (freezing) are methods available through a doctor. Freeze Away is the same freezing method that doctors use on their patients.

### C. Uses

- ▶ For **removing common warts**: common warts are skin-colored, usually appear on the hands and feet and are recognized by the rough “cauliflower-like” appearance of the surface. They are harmless growths that consist of a center of inner skin (or connective) tissue with blood vessels covered with layers of outer skin (or epidermis) tissue.
- ▶ For **removing plantar warts from the bottom of the foot**: plantar warts are recognized by their location only on the bottom of the foot, their tenderness, and the interruption of the footprint pattern. Plantar warts grow inwards and are often flat due to the pressure caused by walking. They are often callused and painful.

Use Freeze Away only if you are sure the skin condition is a common wart or plantar wart. If you treat a skin condition as a wart with Freeze Away and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease.

### D. Warnings

- ▶ Do not use if you cannot see clearly to read the information in the information booklet.
- ▶ Use only as directed. If you do not use Freeze Away exactly as these directions say to use it, or if you use it on any condition that is not a common or plantar wart, it may cause serious burns, permanent scarring of the skin, or blindness.
- ▶ Do not use if you cannot see clearly the wart you are treating. If you mistakenly apply Freeze Away directly to the skin or

use it on conditions other than common or plantar warts, it may cause serious burns and permanent scarring of the skin.

- ▶ Do not use on children under 4 years because it is uncertain how Freeze Away® Wart Remover may affect the child's skin. If you use Freeze Away on a child who is less than 4 years old, you may permanently scar the child's skin.
- ▶ Do not use if you have diabetes or poor blood circulation. Freeze Away works by freezing the wart. The frozen area in people with diabetes or poor blood circulation may not heal as quickly or completely.
- ▶ Do not use if you are pregnant or breast-feeding. It is uncertain how Freeze Away may affect people under these conditions.
- ▶ Do not use on areas with thin skin such as the face, armpits, breasts, bottom, or genitals. If you use Freeze Away on these areas, it may cause burns or permanent scarring.
- ▶ Do not use on irritated skin, on any area that is infected, reddened or showing any signs of inflammation, such as itching or swelling. Treating these areas with Freeze Away will result in worsening of the condition and possible further infection. These conditions may not be warts and should be examined by a doctor. If you treat a skin condition as a wart with Freeze Away and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease.
- ▶ Do not use on moles, birthmarks, warts with hair growing from them, genital (on penis or vaginal areas) warts, or warts on the face or mucous membranes (such as inside mouth, nose, anus, genitals, lips, ears or near eyes). If you use Freeze Away on these areas, it may cause burns, permanent scarring of the skin, or blindness.
- ▶ When using this product, changes in skin pigmentation may occur at the treated site. If you have any concerns, ask a doctor before using this product.

**Use Freeze Away only if you are sure the skin condition is a common wart or plantar wart.** If you treat a skin condition as a wart with Freeze Away 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 Freeze Away 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 or Deliberately Inhale.** Contents are toxic and may cause serious internal damage. Use only in well-ventilated areas. If swallowed or deliberately inhaled, get medical help or contact a Poison Control Center right away.

**For External Use Only.** Use only as directed. If you do not use Freeze Away exactly as these directions say to use it, or if you use it on any condition that is not a common or plantar wart, it may cause serious burns, permanent scarring of the skin, or blindness.

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

## **E. Cautions**

- ▶ Use Freeze Away only in combination with the special disposable applicators provided in this package. Freeze Away may not be effective if used in combination with other applicators.
- ▶ Use one applicator for each wart; use each applicator only once. Do not reuse an applicator or touch the end of the 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 of an area to freeze at one time and may take longer to heal or the area may not heal properly. Do not begin treatment of any other wart until 2 weeks after the final treatment of the previous wart.

- ▶ In most cases, only one treatment is needed for each wart. Plantar warts may need more than one treatment. Warts are usually gone in two weeks after treatment with Freeze Away® Wart Remover. If a wart or part of it is still there two weeks after treatment, you may then safely treat it again. Do not treat each wart with Freeze Away more than four times in total. If 4 treatments have not removed the wart, ask a doctor and do not treat additional warts.
- ▶ The aching/stinging feeling in treated common warts should disappear within a few hours after 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), ask a doctor. The area may have been frozen too deeply and you may need medical attention. The treated area may be sensitive for a few days.
- ▶ Do not inhale vapor/spray and use only in well-ventilated areas. It is uncertain how the vapor/spray will affect the lungs. Breathing vapor/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 stops.

**HIGHLY FLAMMABLE.** Contents under pressure. Do not pierce or burn pressurized can, even after use. Protect from sunlight and do not expose to temperatures above 50°C (120°F). Store between 20° to 25°C (68° to 77°F) and away from heat. Keep away from fire or flame and from sources of sparks or ignition. Do not smoke while using Freeze Away. Piercing the can or exposure to heat may cause it to explode, causing serious injury.

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

See "Warnings" and "Cautions". Use Freeze Away only if you are sure the skin condition is a common wart or plantar wart. If you treat a skin condition as a wart with Freeze Away 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 Freeze Away® Wart Remover work?**

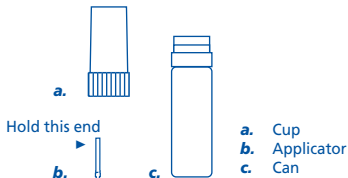
1. Freeze Away freezes warts instantly. The freezing kills both the virus and the infected site. When the applicator is pressed on the wart, freezing begins within a few seconds and the skin will turn white (see Instructions for Use). A slight aching, itching and/or stinging feeling will occur as a result of the freezing. After the applicator is removed, skin color will return and the aching, itching, stinging feeling will quickly decrease, disappearing within a few hours for common warts, but may last for 24 hours for treated plantar warts.
2. After the area thaws and skin color 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.
3. The frozen skin with the treated wart will fall off after about 10 - 14 days. In the meantime, new, healthy 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 for common warts. For plantar warts, the feeling may last 24 hours after the area thaws.
- ▶ Possible changes in skin coloring from white to red.
- ▶ Possible changes in skin pigmentation.
- ▶ Black dots may appear in the middle of the wart after a few days.
- ▶ Possible blistering.

#### **I. Instructions for Use**

- ▶ READ ALL INSTRUCTIONS FOR USE BEFORE BEGINNING.
- ▶ DO NOT USE ON ANY SKIN CONDITION OTHER THAN COMMON WARTS OR PLANTAR WARTS.







#### **CAUTION!**

- ▶ Do not hold the pressurized can near your face, or over parts of your body or clothing.
- ▶ Product should be applied only by adults; do not apply on children under 4 years of age.

#### **TREATMENT TIMES**

After the applicator has absorbed the cold liquid, press and hold it on a 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 callused skin, such as the balls of the foot or the heel, hold the applicator on the plantar wart for 40 seconds or less. Treat plantar warts that are on less callused areas of the foot, such as the arch of the foot or toes, for 20 seconds or less. Callused areas of the foot vary from person to person. If the area of the foot where the plantar wart occurs is not callused, do not apply Freeze Away® Wart Remover for more than 20 seconds.

**DETERMINE YOUR TREATMENT TIME FROM THE CHART BELOW.****Common warts and Plantar warts on toes and arch of foot**

Wart Diameter	Treatment Time
Smaller than  (3/32" [2.5 mm])	10 seconds
 to  (3/32" – 3/16" [2.5 mm – 5.0 mm])	15 seconds
Larger than  (3/16" [5.0 mm])	20 seconds

**Callused Plantar warts on heels and balls of foot**

Wart Diameter	Treatment Time
All sizes	40 seconds

**Maximum Treatment Times for Plantar Warts on Various Parts of Foot**

 20 Second Area

 40 Second Area

Plantar warts may be soaked in warm water for 5 minutes, dried thoroughly and the area filed with an emery board before applying Freeze Away.



Figure 1

Place blue cup on a table or other sturdy surface. Turn pressurized can upside down and align the 3 tabs on the can with the 3 slots in the cup (See Figure 1). Make sure that the cup and the mounted can are aligned and not tilted. (Note: Pressurized can must be upside down to function properly.)



Figure 2

Press straight down on pressurized can and hold for 2 to 3 seconds (See Figure 2). You will hear a hissing sound as cold liquid is discharged into the cup. You may smell some dimethyl ether.



Figure 3

After pressing down on can and discharging the cold liquid into the cup; remove the can from the cup, taking care that the cup does not tip over. Immediately grasp the applicator by the plastic stem and insert the tip into the cup so that the tip rests against the bottom of the cup. The cold liquid within the cup will be absorbed by the tip within 10 seconds (See Figure 3).



Figure 4

Carefully withdraw the activator from the cup and immediately apply the tip to the wart (See Figures 4 and 5). Lightly press and hold the applicator tip on the wart for the treatment time directed in the treatment time chart. Do not swab. Apply Freeze Away® Wart Remover immediately after you remove applicator from the cup and while it is still very cold or it will not work. There will be an aching, itching, stinging sensation as the wart is frozen.



Figure 5



Figure 6

5. After completing the treatment, place the still cold applicator back into the cup (See Figure 6). Set the can and cup containing the used applicator out of reach of children. After 10 minutes dispose of used applicator. Discard the applicator after a single use. Do not reuse applicator or touch the tip of the applicator with bare hands to ensure that you don't reinfect the skin with the wart virus. Retain the cup for future treatments.

For each common wart, only one treatment is necessary in most cases. In two weeks after treatment with Freeze Away, common warts are usually gone. Plantar warts may require more than one treatment. If a wart or part of it is still there two weeks after treatment, you may then safely treat it again. Do not treat each wart with Freeze Away more than four times in total. If 4 treatments have not removed the wart, ask a doctor and do not treat additional warts. Do not apply Freeze Away together with any other method of wart removal because it is uncertain how the combination may affect your skin. Combination usage may result in serious burns and permanent scarring of the skin.

**It is important that the instructions in the Information Booklet are followed exactly. Careless use can cause freezing too deeply and permanently damage nerves and scar the upper layer of skin on fingers and toes.**

### **J. Follow-up Treatment**

- ▶ After treatment, the color of the skin may change, varying from white to red. A blister may form under the wart and an aching/stinging feeling normally will occur for up to a few hours. For plantar warts, the aching/stinging feeling may last 24 hours. If the aching/stinging feeling continues beyond these times (3 hours for common warts and 24 hours for plantar warts) or another problem, such as freezing the skin beyond the size of the wart or loss of feeling occurs, ask a doctor. It is normal for the treated area to be sensitive for a few days.
- ▶ Black dots may appear in the center of the treated wart after a few days.
- ▶ Keep the treated area clean.
- ▶ You may swim or shower.
- ▶ Do not pick or scratch the treated area as this may result in infection.
- ▶ Protect blisters, if necessary, with a gauze or sterile adhesive bandage.
- ▶ Do not puncture blisters. Puncturing blisters will be painful and may result in infection.
- ▶ If infection develops, see a doctor.

Patent Pending

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25318-04

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