

Compound W[®] Freeze Off[®]

Wart Removal System

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A. Contents of Compound W[®] Freeze Off[®] Wart Removal System

An aerosol spray can with a mixture of dimethyl ether and propane, one reusable applicator handle, 8 disposable foam applicators, 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.

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. However, genital warts have been linked to cancer in the cervix.

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, patients often choose to treat warts rather than wait for them to disappear. Treatments for warts include different topical acid preparations, surgical removal, burning or cryotherapy (freezing). Duct tape has also recently been reported in the news to be effective. Liquid nitrogen is the most commonly applied freezing method, but it is only available through the physician. Compound W[®] Freeze Off[®] is an alternative to liquid nitrogen. It contains dimethyl ether and propane (DMEP) and is as effective and well tolerated as liquid nitrogen.

C. What is Compound W[®] Freeze Off[®] Wart Removal System used for?

Compound W[®] Freeze Off[®] 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 center of inner skin (or connective) tissue with blood vessels covered with layers of outer skin (or epidermis) tissue. Common warts are skin-colored, 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 this Information Leaflet. Use only as directed.
- Do not use if you cannot see clearly the wart you are treating. If you mistakenly apply Compound W[®] Freeze Off[®] 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 Compound W[®] Freeze Off[®] 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. Compound W[®] Freeze Off[®] 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 Compound W[®] Freeze Off[®] 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 Compound W[®] Freeze Off[®] will result in worsening of the condition and possible further infection. These conditions may not be warts and should be examined by a doctor.
- 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.

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

Use Compound W[®] Freeze Off[®] only if you are sure the skin condition is a wart.

If you are not sure, consult your doctor. If you treat a skin condition as a wart with Compound W[®] Freeze Off[®] 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 Compound W[®] Freeze Off[®] 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 Center right away.

For External Use Only. Use only as directed. If Compound W[®] Freeze Off[®] 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 Compound W[®] Freeze Off[®] only in combination with the special disposable foam applicators provided in this package. Compound W[®] Freeze Off[®] 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 of 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 Compound W[®] Freeze Off[®]. 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 Compound W[®] Freeze Off[®] more than three times in total. Consult your doctor if three treatments have not led to improvement.
- 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, talk to your doctor. This may mean that the area has been frozen too deeply and medical attention may be needed.
- Do not inhale vapor/spray and use only in well ventilated areas because 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 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 Compound W[®] Freeze Off[®]. Piercing the container or exposure to heat may cause the container to explode, causing serious injury. Do not breathe the vapor/spray and use only in well ventilated areas because it is uncertain how the vapor/spray will affect the lungs. Breathing vapor/spray may be toxic.

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

See "Warnings" and "Cautions." Use Compound W[®] Freeze Off[®] only if you are sure the skin condition is a wart. If you are not sure, consult your doctor. If you treat a skin condition as a wart with Compound W[®] Freeze Off[®] 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 Compound W[®] Freeze Off[®] work?

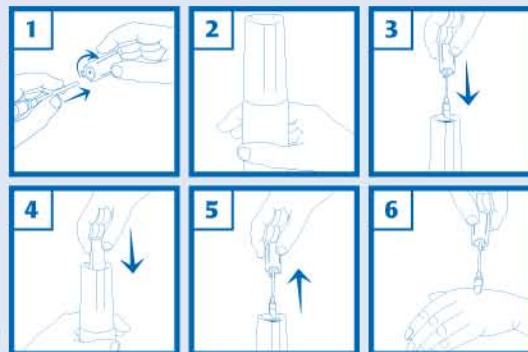
1. Compound W[®] Freeze Off[®] freezes warts on the spot. The freezing kills both the virus and the infected skin. When the foam applicator is pressed on the wart, freezing begins within a few seconds and the skin will turn white (see diagram and instructions for use). A slight aching, itching and/or stinging feeling will occur as a result of the freezing. After the foam applicator is removed, color will return and the aching, itching, stinging feeling will quickly decrease, disappearing within a few hours.
2. After the area thaws and 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 skin will have formed under the blister.

H. Side Effects

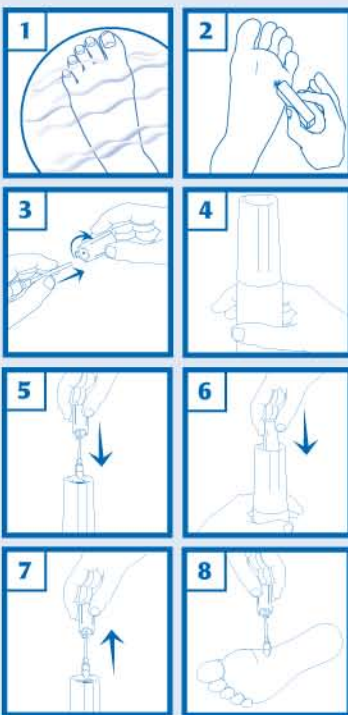
- A stinging, itching, aching feeling during and after freezing that quickly decreases after the area thaws.
- Possible changes in coloring from white to red. • Possible blistering.
- Black dots may appear in the middle of the wart after a few days.

I. Instructions for Use (Common Warts)

1. Attach the applicator (stick with the foam tip) to the handle as shown. Firmly press the stick into the opening in the middle of the handle.
2. 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.**
3. Insert the handle, with the applicator attached, into the top of the canister. Line up notches in handle with the openings in the top of the canister.
4. Keeping the canister upright and holding the canister firmly with one hand, press the handle downward until you hear a hissing sound. Continue to hold down for 2 to 3 seconds to saturate the applicator. You will hear a hissing sound for the entire period.
5. Remove the handle with the attached applicator from the canister. The foam applicator should be saturated with cold liquid and have a frosty appearance. You may also smell some dimethyl ether.
6. Lightly press the foam applicator for several seconds on the wart that is to be frozen. Do not swab. Compound W[®] Freeze Off[®] should be applied immediately. **Hold the foam applicator on common warts for 20 seconds or less.** Smaller warts may require less than 20 seconds. See "Application Times" table & Figure 1 below for proper times.



- 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, or stinging sensation during treatment.
- Discard the foam applicator after a single use, taking care not to touch the foam applicator with bare hands, to ensure that re-infection with the wart virus does not occur. Wash hands after treatment.



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 pumice stone (not included) before applying Compound W[®] Freeze Off[®].
3. Attach the applicator (stick with the foam tip) to the handle as shown. Firmly press the stick into the opening in the middle of the handle.
4. 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.**
5. Insert the handle, with the applicator attached, into the top of the canister. Line up notches in handle with the openings in the top of the canister.
6. Keeping the canister upright and holding the canister firmly with one hand, press the handle downward until you hear a hissing sound. Continue to hold down for 2 to 3 seconds to saturate the applicator. You will hear a hissing sound for the entire period.
7. Remove the handle with the attached applicator from the canister. The foam applicator should be saturated with cold liquid and have a frosty appearance. You may also smell some dimethyl ether.
8. Lightly press the foam applicator for several seconds on the wart that is to be frozen. Do not swab. Compound W[®] Freeze Off[®] should be applied immediately. **Hold the foam applicator on plantar warts on areas with thicker or calloused skin, such as the ball of the foot or the 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 the toes, for 20 seconds or less (see Figure 1).** See "Application Times" table & chart below for proper times.
- When treating warts on the top of toes, slowly move the toes while administering treatment. There may be an aching, itching, or stinging sensation during treatment.
- Discard the foam applicator after a single use, taking care not to touch the foam applicator with bare hands, to ensure that re-infection with the wart virus does not occur. Wash hands after treatment.

I. Instructions for Use (Common and Plantar Warts)

For each common wart, only one treatment is necessary in most cases. Use one foam applicator for one treatment. Plantar warts may require more than one treatment. In two weeks after treatment with Compound W[®] Freeze Off[®], common warts are usually gone. 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 Compound W[®] Freeze Off[®] more than three times in total. Consult your doctor if three treatments have not led to improvement. Do not apply Compound W[®] Freeze Off[®] 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 Leaflet are followed exactly. Careless use can cause freezing too deeply, causing permanent damage to the uppermost layer of skin on fingers and toes. This may result in permanent scars or nerve damage.

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 Compound W[®] Freeze Off[®] for more than 20 seconds.

	WART DIAMETER	TREATMENT TIME
Common warts and plantar warts on toes and arch of foot	Smaller than ● 3/32 in (2.5 mm)	10 seconds
Common warts and plantar warts on toes and arch of foot	● to ● 3/32 - 3/16 in (2.5 - 5.0 mm)	15 seconds
Common warts and plantar warts on toes and arch of foot	Larger than ● 3/16 in (5.0 mm)	20 seconds
Calloused Plantar warts on heels and balls of feet	All sizes	40 seconds or less

K. Follow-up Treatment

- After application, 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. 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 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.

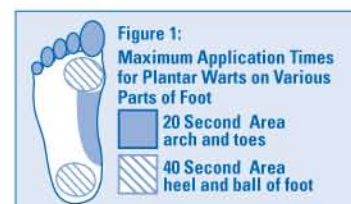


Figure 1:
Maximum Application Times
for Plantar Warts on Various
Parts of Foot