

Compound W[®] FREEZE OFF[®]

WART REMOVER

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A. Indications for use

Compound W Freeze Off[®] Advanced is indicated for the over-the-counter treatment of common warts and plantar warts, for patients aged 4 years and older.

B. Contents of Compound W Freeze Off[®] Advanced

A pressurized canister filled with 50 mL of the compressed liquid gas dimethyl ether. A custom application unit used to administer the cold delivered by the cryogen to the wart. This information leaflet in which you can read about the product, how it works, how to use the product to treat warts, warnings and limitations.

C. Background on warts

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.

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 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). Liquid nitrogen is the most commonly applied freezing method, but it is only available through the physician. Compound W Freeze Off[®] Advanced is an alternative to liquid nitrogen. It contains dimethyl ether and is as effective and well tolerated as liquid nitrogen.

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 clearly see the wart you are treating. If you mistakenly apply Compound W Freeze Off[®] Advanced on the 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[®] Advanced may affect the child's skin.
- Do not use if you are diabetic or if you have poor blood circulation. Compound W Freeze Off[®] Advanced 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[®] Advanced may affect patients under these conditions.
- Do not use on areas with thin skin such as the face, armpits, breasts, bottom, or genital area. 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[®] Advanced 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, genital, lips, ears or near eyes). Use on these areas may cause burns and permanent scarring of the skin or blindness.

Use Compound W Freeze Off[®] Advanced 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[®] Advanced 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[®] Advanced has been applied to them. If product gets into eyes, flush with water for 15 minutes and call medical help right away.

Do not Swallow. Content is toxic and may cause serious internal damage. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

For External Use Only. Use only as directed. If Compound W Freeze Off[®] Advanced 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. Content is hazardous if swallowed, inhaled, sprayed on parts other than the wart, or exposed to heat.

E. Cautions

Do not use Compound W Freeze Off[®] Advanced:

- if you do not hear the "hissing" sound during activation (release of aerosol), and/or;
- if the "hissing" sound continues after activation, and/or;
- if the tip does not become cold after activation. An "icy surface" should become visible on the metal tip.

In case one or more of the above mentioned conditions are not fulfilled, the device may not be functioning properly. Failure of the device may lead to injury or insufficient/incomplete treatment.

- The metal tip is coated with nickel, which may cause allergic reaction.
- If being used by more than one person and/or after each application, clean the applicator with alcohol on a small piece of cloth.
- If there is more than one wart on a finger or toe, only treat one wart at a time. If there are warts that are closer than 1 inch apart on other areas of the body, do not treat them at the same time. Freezing warts that are too close together at the same time could lead to over-freezing of the area and may cause significant discomfort, take longer to heal, or the area may not heal properly. Treat each remaining wart 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[®] Advanced. If a wart or a part of it is still there two weeks after treatment, you may then safely treat again. Do not treat each wart with Compound W Freeze Off[®] Advanced 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 lasts beyond this time, 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.
- Always place can upright on covered surface to protect surface finish.
- Improper use may cause leakage of the liquefied gas. If leakage on skin occurs, wipe away product immediately and rinse skin thoroughly.

Extremely Flammable. Content under pressure. Do not pierce or burn aerosol spray can, even after use. Protect from sunlight and do not expose to temperature above 50°C (120°F). Store at room temperature away from heat. Keep away from fire or flame and from source of sparks or ignition, including mobile phones, radios, and other electrical appliances. Do not smoke while using Compound W Freeze Off[®] Advanced. Piercing the container or exposure to the heat may cause the container to explode, causing serious injury. Do not breathe 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[®] Advanced 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[®] Advanced 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® Advanced work?

- 1. Compound W Freeze Off® Advanced freezes warts on the spot. The freezing kills both the virus and the infected skin. When the applicator is pressed (applied) 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 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

For safe and effective use, the times in the instructions need to be followed exactly. It is highly recommended to have a timer ready and read the instructions once completely before starting use.

Place the can upright on a covered table and lift off the cap. Keep can upright throughout Steps 1-3.

Put the cap back, aligning the arrow icon with the freeze icon.

Press the cap down firmly for 3 seconds (do not exceed 3 seconds). You will hear a hiss.

While can is still upright, take off the cap. Wait 2 seconds for the metal tip to freeze, then precisely apply the frozen metal tip on the wart, (maximum 20 seconds for common warts, 40 seconds for plantar warts).

I. Instructions for use (Common Warts)

- 1. Remove the cap and place the can upright on a covered table or flat surface.
- 2. **Keep the can in the upright, vertical position;** put the cap back aligning the arrow icon of the cap with the freeze icon of the can.
- 3. Press the cap down for 3 seconds (**DO NOT EXCEED 3 SECONDS**). You will hear the activation sound (hiss).
- 4. While can is still upright, take off the cap. Wait 2 seconds for the metal tip to freeze, then precisely apply the frozen metal tip on the common wart (hand) for a maximum of 20 seconds. Follow the application time included in the instruction leaflet.

Replace the cap in locked position for storage.

I. Instructions for use (Plantar Warts)

Soak foot with plantar wart for 5 min. in warm water. Dry thoroughly. File the plantar wart area with a pumice stone or pumice file (not included) before applying Compound W Freeze Off® Advanced.

- 1. Remove the cap and place the can upright on a covered table or flat surface.
- 2. **Keep the can in the upright vertical position;** put the cap back aligning the arrow icon of the cap with the freeze icon of the can.
- 3. Press the cap down for 3 seconds (**DO NOT EXCEED 3 SECONDS**). You will hear the activation sound (hiss).
- 4. While can is still upright, take off the cap. Wait 2 seconds for the metal tip to freeze, then precisely apply the frozen metal tip on the plantar wart (foot) for a maximum of 40 seconds. Follow the application time included in the instruction leaflet.

Replace the cap in locked position for storage.

Comfort pads (not included) 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.

I. Instructions for use (Common and Plantar Warts)

For each common wart, only one treatment is necessary in most cases. Plantar warts may require more than one treatment. In two weeks after treatment with Compound W Freeze Off® Advanced, 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® Advanced more than three times in total.

Allow the metal tip to reach room temperature after each application before reactivating for use on common warts or plantar warts - this takes approximately 5 minutes. 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.

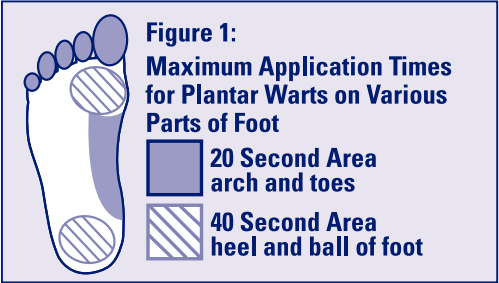
Consult your doctor if three treatments have not led to improvement. Do not apply Compound W Freeze Off® Advanced together with any other method of wart removal because it is uncertain how the combination may affect your skin. Combination usage may result in serious burns and permanent scarring of the 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 the skin on fingers and toes. This may result in permanent scars or nerve damage.

J. Application times

Precisely apply the frozen metal tip on the common wart (hand) 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 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® Advanced 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	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



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 less 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.

Compound W Freeze Off® Advanced contains: Dimethyl ether

The product can be used until the expiration date indicated on both the carton and the pressurized canister.

Questions? 1-800-443-4908
For more information please visit CompoundW.com

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WART REMOVER SYSTEM FOR
COMMON AND PLANTAR WARTS

ADVANCED

CompoundW®
WART REMOVER

**FREEZE
OFF**®