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Compound W[®]

WART REMOVER



Nitrous Oxide

MAXIMUM FREEZE

NITRO FREEZE™

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A. Indications for use

Compound W NitroFreeze[®] is intended for over-the-counter treatment of common warts and plantar warts in adults and children four years of age or older.

B. Contents of Compound W NitroFreeze[®]

A pressurized canister filled with 7.5 grams of the compressed liquid gas, nitrous oxide. Six disposable foam applicator tips. 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

Warts are growths on the skin or mucus 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 mucus 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.

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 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 a physician. Compound W NitroFreeze[®] is an alternative to liquid nitrogen. It contains nitrous oxide (N₂O) 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 NitroFreeze[®] on conditions that are not warts, it may cause serious burns (frostbite) and permanent scarring of the skin.

- Do not use on children under the age of 4 years. It is uncertain how Compound W NitroFreeze[®] may affect the child's skin.
- Do not use if you are diabetic or if you have poor blood circulation. Compound W NitroFreeze[®] 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 NitroFreeze[®] may affect patients under these conditions.
- Do not use on area with thin skin such as face, armpits, breasts, bottom, or genitals. Use on these areas may cause burns (frostbite) and permanent scarring.
- Do not use on the 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 NitroFreeze[®] 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 mucus membranes (such as inside mouth, nose, anus, genital, lips, ears or near eyes). Use on these areas may cause burns (frostbite) and permanent scarring of the skin or blindness.

Use Compound W NitroFreeze[®] 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 NitroFreeze[®] 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 NitroFreeze[®] 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. 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 NitroFreeze[®] 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 (frostbite) 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, inhaled, sprayed on body parts other than warts, or exposed to heat.

E. Cautions

Do not use Compound W NitroFreeze[®]:

- if you do not hear the "hissing" sound during activation (release of gas), and/or;
- if the "hissing" sound continues after activation, and/or;
- if the foam tip does not become cold after activation (the tip should have a frosty appearance).

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

- Use Compound W NitroFreeze[®] only in combination with the special disposable **foam applicators** provided in this package. Compound W NitroFreeze[®] may not be effective if used in combination with other applicators, foam or otherwise.

READ ALL LABELS AND ENTIRE INFORMATION LEAFLET BEFORE USE. KEEP FOR REFERENCE.

VISIT OUR WEBSITE AT WWW.COMPOUNDW.COM TO VIEW A DEMONSTRATION OF ACTIVATION AND USAGE OF THE COMPOUND W NITROFREEZE[®] PEN.

- Use one **foam applicator** for one treatment for each wart; use each **foam applicator** only once. Do not reuse **foam applicator** or touch 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. 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 NitroFreeze[®]. If a wart or a 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 NitroFreeze[®] 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.

- 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.

Content under pressure. Never pierce or burn, even after use - the device is under high pressure and cannot be opened. Protect from sunlight and do not expose to temperatures above 50° C (120° F) before first use or 35° C (95° F) after first use; exposure to temperatures above 35° C (95° F) after first use will activate a safety feature that disables the device permanently. Store at room temperature away from heat. Nitrous oxide is a non-flammable gas, but it will support combustion in case of fire. Keep away from flames or materials that burn easily, or are sources of sparks or ignition, including mobile phones, radios, and other electrical appliances. Do not smoke or use near an open flame. Do not inhale nitrous oxide - symptoms can include feeling dizzy or confused and headache.

F. What to do if you are uncertain if the condition is a wart? See "Warnings" and "Cautions." Use Compound W NitroFreeze[®] 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 NitroFreeze[®] 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 NitroFreeze[®] work?

1. Compound W NitroFreeze[®] 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 skin coloring from white to red, or loss of skin color.
- Use of the device may cause permanent skin discoloration (lighter or darker skin), which may be more prominent on darker skin tones.
- Possible blistering.
- Black dots may appear in the middle of the wart after a few days.

STOP: DO NOT REMOVE THE CAP FROM THE PEN UNTIL STEP 3.



STEP 1: PREPARE (FIRST USE ONLY)

DO NOT REMOVE CAP.

Consult the figure in section J to confirm application time based on the size and location of the wart.

Forcefully turn the white pen ONE FULL TURN in the direction of the arrow until you hear a CLICK.

You do not need to repeat this step ever again.

STEP 2: ACTIVATE

For plantar warts: Soak foot for 5 minutes in warm water. File the wart down with a pumice stone or pumice file before treating wart. Dry thoroughly.

Place NitroFreeze[™] upright on a table with the clear cap down. Hold the clear plastic cap with a steady grip. With the other hand, **firmly push the white pen downwards continuously for exactly 2 seconds once hissing starts.**

If you do not hear a hissing sound, go back to Step 1.

Pushing for longer will waste useful treatments. Pushing for shorter will reduce the freeze effect.

STEP 3: REMOVE CAP

Remove the cap. The applicator tip should have a frosty appearance. USE PEN IMMEDIATELY.

If there is no frosty appearance, repeat step 2.

STEP 4: TREAT

Immediately press the tip firmly against the wart.

• Follow the application time for your wart shown in the Diagram and Table in section J.

Maximum 20 seconds on hands, fingers and arms.
Maximum 40 seconds on feet.

• Wait at least two (2) minutes after use, then **dispose of foam applicator tip.** **DO NOT** reuse applicator tip or touch the applicator tip with bare hands to ensure you do not re-infect your skin with the wart.

• Insert a new foam applicator tip into the pen and replace the cap. Compound W NitroFreeze[®] is now ready for future use. **Store at room temperature away from heat.**

Comfort pads (not included) can be used to protect the tender plantar wart area after treatment has been completed. Apply adhesive side of pad to skin with hole directly over the small tender spot.

The wart will fall off within 10-14 days. If not, repeat steps 2, 3 and 4.

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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 NitroFreeze[®], 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 NitroFreeze[®] more than three times in total. Consult your doctor if three treatments have not led to improvement. Do not apply Compound W NitroFreeze[®] 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 (frostbite) 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 foam 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[®] NitroFreeze[™] for more than 20 seconds.

Maximum Application Times for Common and Plantar Warts on Various Parts of Foot

Common and Plantar Warts on toes and arch of foot	
Wart Diameter	Treatment Time
Smaller than 3/32 in. (2.5 mm) < ●	10 seconds
3/32 - 3/16 in. (2.5 - 5.0 mm) ● to ●	15 seconds
Larger than 3/16 in. (5.0 mm) > ●	20 seconds
Callused Plantar Warts on heels and balls of foot	
Wart Diameter All Sizes	Treatment Time
 40 Second Area	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 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.

Compound W NitroFreeze[®] contains: Nitrous oxide

The product can be used until the expiration date indicated on the carton. The Compound W NitroFreeze[®] pen will expire 6 weeks after first activation.

Questions? 1-800-443-4908

For more information please visit CompoundW.com