

CompoundW

WART REMOVER®

DUAL POWER®

FREEZE OFF®

2-IN-1 KIT

FOR LARGE WARTS

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- A. Contents of Compound W Dual Power®**
- Compound W Freeze Off® Can - an aerosol spray can with a mixture of dimethyl ether and propane
 - 1 reusable applicator handle
 - 8 disposable foam applicators
 - Compound W® Fast-Acting Liquid wart remover
NET WT 0.31 fl oz (9 mL)
 - 12 comfort pads
 - 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. Risks

Careless use can cause freezing too deeply, causing permanent damage to the uppermost layer of skin on fingers and toes. It may cause burns and permanent scarring of the skin or blindness. See Warnings and Cautions. It is important that the instructions in the Information Leaflet are followed exactly.

C. Benefits

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.

Treatments for warts include different topical acid preparations, surgical removal, burning or cryotherapy (freezing).

Compound W Dual Power® is a convenient combination of freeze therapy and liquid treatment for contagious common and plantar warts.

Compound W Dual Power® is used for the over-the-counter removal of common and plantar warts. If you treat a skin condition with **Compound W Dual Power®** and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease. Use **Compound W Dual Power®** exactly as directed in this Information Leaflet. If you do not follow the directions, you may injure the skin.

D. Uses

Compound W Dual Power® is used for the over-the-counter removal of common and plantar 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). 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.

E. Warnings

For External Use Only. Use only as directed. If **Compound W Dual Power®** 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 or blindness.

Compound W Freeze Off® Can:

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 120°F (50°C). Store at room temperature away from heat. Keep away from fire or flame and from sources of sparks or ignition, including mobile phones, radios, and other electrical appliances. Do not smoke while using Compound W Dual Power®. Piercing the container or exposure to 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.

- 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 Dual Power®** 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 Dual Power®** 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 Dual Power®** 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 Dual Power®** 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 Dual Power®** 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.

Use Compound W Dual Power® 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 Dual Power®** 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 Dual Power®** from the can 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 Inhale. Contents are toxic and may cause serious internal damage. Use only in well-ventilated areas. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Changes in skin pigmentation may occur at the treated site. If you have any concerns, ask a doctor before using this product.

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. Individual parts may present a choking hazard.

Compound W Dual Power®
Fast-Acting Liquid Wart Remover:

Drug Facts

Active ingredient

Salicylic acid 17% w/wWart remover

Uses

■ For the removal of common and plantar warts. The common wart is easily recognized by the rough "cauliflower-like" appearance of the surface. ■ The plantar wart is recognized by its location only on the bottom of the foot, its tenderness and the interruption of the footprint pattern.

Warnings

For external use only.
Extremely Flammable. Keep away from fire or flame.

Do not use

- on irritated skin or on any area that is infected or reddened.
- on moles, birthmarks, warts with hair growing from them, genital warts or warts on the face or mucous membranes.
- if you have diabetes or poor blood circulation.

When using this product

- avoid contact with eyes. If product gets into the eye, flush with water for 15 minutes.
- avoid inhaling vapors.
- cap bottle tightly and store at room temperature away from heat.

Stop use and ask a doctor if discomfort persists.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- 24 hours after treating with Compound W Freeze Off® can, wash affected area and dry thoroughly.
- Using applicator, apply one drop of Compound W® Fast-Acting Liquid at a time to sufficiently cover each wart.
- Let dry.
- Repeat this procedure twice daily for two weeks.
- Self-adhesive comfort pad may be used to cushion wart. Remove comfort pad before re-applying liquid.

If the wart has not disappeared after 2 weeks, you may start another treatment cycle.

Do not treat wart with more than 3 treatment cycles of Compound W Dual Power®.

Other information

- Store between 20° to 25°C (68° to 77°F).
- Keep tightly closed.
- Skin discoloration may occur during or after use.

Inactive ingredients

alcohol, camphor, castor oil, collodion, ether, ethylcellulose, hypophosphorous acid, menthol, polyorbate 80

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

F. Cautions

- Use **Compound W Freeze Off® Can** only in combination with the special disposable **foam applicators** provided in this package and **Compound W® Fast-Acting Liquid** provided in this package. **Compound W Dual Power®** 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. 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.
- If a wart or part of it is still there two weeks after treatment, you may then safely freeze and apply liquid medication again. Do not treat each wart with **Compound W Dual Power®** more than three times in total. Consult your doctor if three treatments have not led to improvement.

■ After freezing, 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.

■ 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.

■ During the treatment cycle, you may experience discomfort such as burning, stinging, itching or cracked or broken skin or discoloration of the treated area. The skin may also look flaky and dry. If discomfort worsens during or after treatment, see a doctor. You may have developed an infection.

■ Always place **Compound W Freeze Off® 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.

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

See **"Warnings"** and **"Cautions"**.
Use Compound W Dual Power® 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 Dual Power®** and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease.

H. How does Compound W Dual Power® work?

1. **Compound W Freeze Off® Can** 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. 24 hours after freezing, the **Compound W Dual Power® Fast-Acting Liquid** is applied to the treated area twice daily.
4. 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.

I. 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.

J. Instructions for Use

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

WARNING!

- **Do not hold the spray 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.**

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® Can** 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

Plantar warts may be soaked in warm water for 5 minutes and dried thoroughly and the area may be filed with an emery board before treating with Compound W Dual Power®. Discard emery board after use.

DIRECTIONS
One Time Treatment Cycle
Assembly:

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 upright and firmly on a covered 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. After releasing the **handle**, wait 30 seconds, and then 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 Dual Power®** should be applied immediately after removing the applicator from the canister. See **"Application Times" table & Diagram 1 above for proper times.**
7. **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.

Apply Liquid:

8. 24 hours after treating with **Compound W Freeze Off® Can**, wash the treated wart and dry thoroughly.
9. Using applicator, apply one drop at a time to sufficiently cover each wart. Let dry.
10. Apply liquid twice daily for 2 weeks.
11. Self-adhesive comfort pad may be used to cushion wart before re-applying liquid. Remove comfort pad before re-applying liquid.

If the wart has not disappeared after 2 weeks, you may start another treatment cycle. Do not treat wart with more than 3 treatment cycles of Compound W Dual Power®.
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.

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. For plantar warts, the aching/stinging feeling may last 24 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.

During the freezing cycle, you may experience discomfort such as burning, stinging, itching or cracked or broken skin or discoloration of the treated area. The skin may also look flaky and dry. If discomfort worsens during or after treatment, see a doctor. You may have developed an infection.

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