

**Congelac**  
**PARA ELIMINACIÓN**  
**PARA LAS VERRUGAS CO**

## Rapid Freeze WART REMOVER

**FOR COMMON & PLANTAR WARTS**

Distribuido por: CVS Pharmacy Inc. Woon  
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| <b>A. Contenido del CVS/pharmacy® Congelación Rápida para Eliminación de Verrugas</b>            |           |

Una lata de aerosol que contiene una mezcla de soporte reutilizable para el aplicador, este folle leer acerca del producto, cómo funciona, cómo las verrugas, advertencias, limitaciones y aplicadores desechables de 7 mm cada uno.

### B. Información sobre las verrugas

Las verrugas son brotes en la piel o en las membranas mucosas y pueden aparecer en cualquier parte del cuerpo de una misma persona a otra parte directa o por el contacto con las escamas de la piel. Las verrugas desaparecen espontáneamente, pero solo se consigue eliminarlas mediante tratamientos médicos. Entre los tratamientos para las verrugas se encuentran las preparaciones ácidas tóxicas, cirugía, electrocoagulación (congelamiento). Por las noticias publicadas resulta eficaz. El nitrógeno líquido es comúnmente aplicado, pero solo se consigue eliminarlas mediante tratamientos médicos. Entre los tratamientos para las verrugas se encuentran las preparaciones ácidas tóxicas, cirugía, electrocoagulación (congelamiento). Por las noticias publicadas resulta eficaz. El nitrógeno líquido es comúnmente aplicado, pero solo se consigue eliminarlas mediante tratamientos médicos.

CVS/pharmacy® Congelación Rápida para Eli

alternativa al nitrógeno líquido. Contiene dimetil etilamina y un bien tolerado como el nitrógeno

**C. ¿Para qué se utiliza el CVS/pharmac para Eliminación de Verrugas?**

El CVS/pharmacy® Congelación Rápida para i utiliza para la eliminación de las verrugas cor plantares en el pie. Las verrugas comunes y inofensivos compuestos por piel interior cen sanguíneos cubiertos por capas de piel exte verrugas comunes son del color de la piel, a manos y los pies, y son fáciles de reconocer al de una coliflor en la superficie. Las verru: planta de los pies y con frecuencia son plana caminar. Las verrugas plantares crecen haca callosas y pueden ser muy dolorosas. El pati liso en el área donde aparece la verruga plan pie lo largo de la superficie de las verrugas.

### D. Advertencias

- No utilice el producto si no puede ver con su información del folleto informativo. Utilice lo
- No lo utilice si no puede ver con claridad la por error se aplica el CVS/pharmacy® Cong Verrugas directamente sobre la piel o verrugas, éste puede causar quemaduras e
- No lo utilice en niños menores de cuatro a efectos del CVS/pharmacy® Congelación R Verrugas en la piel de los niños. Si se utiliz años, puede causar cicatrices permanentes
- No utilice el producto si padece diabetes o tie CVS/pharmacy® Congelación Rápida para Eli congelando la verruga. El área congelada en i y sufren de problemas de circulación podria i
- No lo utilice si está embarazada o en periodo sobre los efectos del CVS/pharmacy® Cong Verrugas en las personas con los padecimie
- No utilice en áreas de la piel como la cara, los genitales. El uso en estas áreas puede e permanentes.
- No use sobre piel irritada, ni en ninguna área q muestre señales de inflamación como picazón con el CVS/pharmacy® Congelación Rápida p empeoramiento de la afección cualquier posib afecciones podrían no ser verrugas y deben si
- No lo utilice en lunares, marcas de nacimie verrugas genitales (en el la zona del pene c rostro o las membranas mucosas (dentro i genitales, los labios, los oídos o cerca de l puede causar quemaduras y cicatrices de

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### A. Contents of CVS/pharmacy® Rapid Freeze Wart Remover

An aerosol spray can with a mixture of dimethyl ether and propane, one reusable applicator holder, 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, and seven disposable foam applicators each 7 mm.

## 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. CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover used for?**

CVS/pharmacy® Rapid Freeze Wart Remover 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 callused, 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 the information leaflet. Use only as directed.
- Do not use if you cannot clearly see the wart you are treating. If you mistakenly apply CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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. CVS/pharmacy® Rapid Freeze Wart Remover 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 breastfeeding. It is uncertain how CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover only in combination with the special disposable **foam applicators** provided in this package. CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover. 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.

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

See "Warnings" and "Cautions". Use CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover 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 CVS/pharmacy® Rapid Freeze Wart Remover work?**

1. CVS/pharmacy® Rapid Freeze Wart Remover 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.

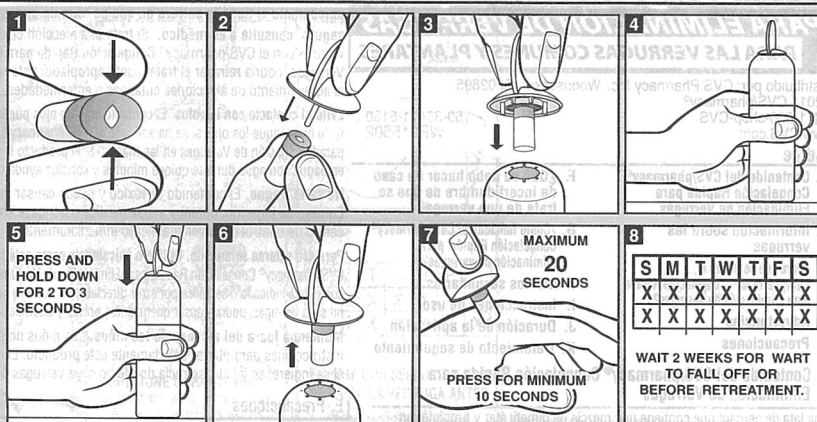
#### 4. Side Effects

- 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.

# INFORMATION LEAFLET CAREFULLY BEFORE USE. KEEP FOR REFERENCE.

## I. Instructions for Use (Common Warts)

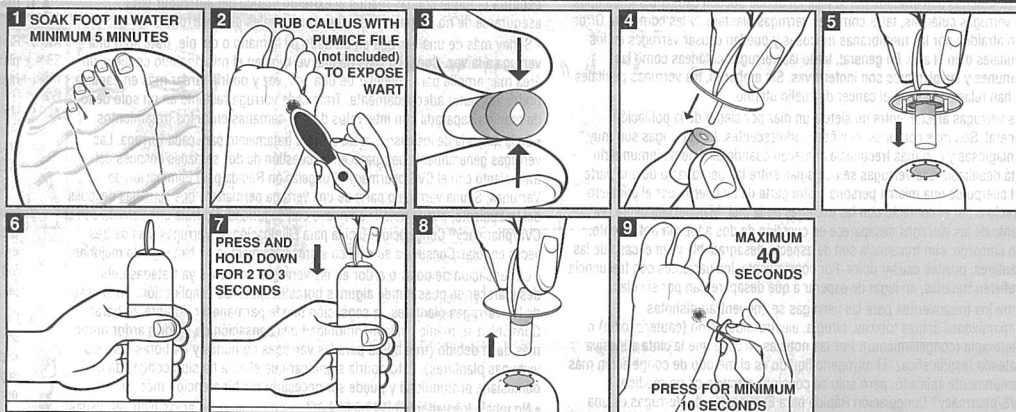
1. Select a foam applicator and squeeze the colored end of the foam applicator between the thumb and index finger until a small opening appears.
2. Slide the opening on the colored end of the foam applicator over the stick of the applicator holder until the stick is no longer visible.
3. Insert the applicator holder with the attached foam applicator into the opening on the top of the aerosol can so that the foam applicator is no longer visible.
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. Holding the aerosol can firmly with one hand at the bottom, firmly press down on the applicator holder with the other hand until you hear a hissing sound. Continue to press down for 2 to 3 seconds. You will hear a hissing sound for the entire period.
6. Pull the applicator holder with the attached foam applicator out of the valve. The white end of the foam applicator will be saturated with cold liquid and you will see condensation (white frosty appearance). You may smell some dimethyl ether.
7. Leave the foam applicator on the applicator holder and, grasping the applicator holder, lightly press the white tip of the foam applicator for several seconds on the wart that is to be frozen. Do not swab. CVS/pharmacy® Rapid Freeze Wart Remover 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). 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, stinging sensation. Wait 2 minutes before using a tissue to remove the foam applicator from the applicator holder. Discard the foam applicator after a single use. Do not reuse foam applicator or touch the white end of the foam applicator with bare hands to ensure that reinfection with the wart virus does not occur.

## I. 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 a pumice stone or pumice file (not included) before applying CVS/pharmacy® Rapid Freeze Wart Remover.
3. Select a foam applicator and squeeze the colored end of the foam applicator between the thumb and index finger until a small opening appears.
4. Slide the opening on the colored end of the foam applicator over the stick of the applicator holder until the stick is no longer visible.
5. Insert the applicator holder with the attached foam applicator into the opening on the top of the aerosol can so that the foam applicator is no longer visible.
6. 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.
7. Holding the aerosol can firmly with one hand at the bottom, firmly press down on the applicator holder with the other hand until you hear a hissing sound. Continue to press down for 2 to 3 seconds. You will hear a hissing sound for the entire period.
8. Pull the applicator holder with the attached foam applicator out of the valve. The white end of the foam applicator will be saturated with cold liquid and you will see condensation (white frosty appearance). You may smell some dimethyl ether.
9. Leave the foam applicator on the applicator holder and, grasping the applicator holder, lightly



press the white tip of the foam applicator for several seconds on the wart that is to be frozen. Do not swab. CVS/pharmacy® Rapid Freeze Wart Remover should be applied immediately. Hold the foam applicator on plantar warts on areas with thicker or callused skin, such as the balls of the foot or the heel, for 40 seconds or less. Treat plantar warts occurring on less callused areas of the foot, such as the arch of the foot or toes, for 20 seconds or less (see Figure 1). There will be an aching, itching, stinging sensation. Wait 2 minutes before using a tissue to remove the foam applicator from the applicator holder. Discard the foam applicator after a single use. Do not reuse foam applicator or touch the white end of the foam applicator with bare hands to ensure that reinfection with the wart virus does not occur.

## I. Instructions for Use (Common and Plantar Warts)

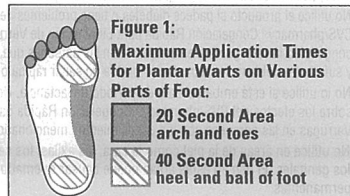
For each common wart, only one treatment is necessary in most cases. Use one foam applicator for one treatment. Plantar warts may require more than one treatment. In two weeks after treatment with CVS/pharmacy® Rapid Freeze Wart Remover, common warts are usually gone. If a wart or part of it is still there two weeks after treatment, you may then safely treat it again. Do not treat warts with CVS/pharmacy® Rapid Freeze Wart Remover more than three times in total. Consult your doctor if three treatments have not led to improvement. Do not apply CVS/pharmacy® Rapid Freeze Wart Remover 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 or an area of the foot with thicker or callused 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 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 CVS/pharmacy® Rapid Freeze Wart Remover 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         |
| Callused 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.
- You may swim or shower.
- 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.
- Keep the treated area clean.
- Do not pick or scratch the treated area as this may result in infection.