

Acetocaustin®

Wart and Verruca Freeze Treatment

PLEASE READ INSERT CAREFULLY BEFORE USING ACETOCAUSTIN WART AND VERRUCA FREEZE TREATMENT. WE ADVISE YOU TO KEEP THIS LEAFLET, YOU MAY NEED TO READ IT AGAIN.

1. CONTENTS OF ACETOCAUSTIN WART AND VERRUCA FREEZE TREATMENT

A pressurized canister filled with 50ml (at date of manufacture) of the compressed liquid gas dimethyl- ether. A custom application unit (applicator) is used to administer the cold delivered by the cryogen to the wart.

2. 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 verrucas and common warts.

Verrucas are similar to warts but occur only on the soles of the feet or underneath the toes. Generally painful, they often look like a small white ring of skin with black dots in the centre. Verrucas are also contagious and can be transmitted to another person by contact with a wet surface such as a floor. Other versions of the virus are attracted to the mucous membranes where they can cause warts on the genitals or anus.

Skin-related warts such as common warts and verrucas 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 verrucas. 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. Acetocaustin Wart and Verruca Freeze Treatment is an alternative to liquid nitrogen.

3. WHAT IS ACETOCAUSTIN WART AND VERRUCA FREEZE TREATMENT USED FOR?

Intended purpose: Acetocaustin Wart and Verruca Freeze Treatment is indicated for the over-the-counter treatment of common warts and plantar warts (verruccas), for patients aged 4 years and older.

Common warts and verrucas 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.

Verrucas only occur on the bottom of the feet and are often flat due to the pressure caused by walking. Verrucas grow inward, are often calloused, and can be very painful. The footprint pattern is smooth over the area where the verruca occurs because "skin lines" (or papillary lines) do not appear across the surface of verrucas.

4. HOW DOES ACETOCAUSTIN WART AND VERRUCA FREEZE TREATMENT WORK?

Acetocaustin Wart and Verruca Freeze Treatment freezes warts on the spot on fingers, hands and feet. The freezing destroys affected tissue. When the applicator is first cooled and then 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 should quickly decrease, disappearing within a few hours.

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 (sometimes filled with blood) may form under the wart within a few days. You may not see this easily. 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.

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and to the competent authority of the Member State in which the user is established.

For more information about Acetocaustin Wart and Verruca Freeze Treatment visit www.dryglo.com. For all product enquiries, please contact the distributor.



Fred. Roeskestraat 115
1076 EE Amsterdam
The Netherlands

5. INSTRUCTIONS FOR USE ON COMMON WARTS

1. Place the aerosol can on a hard surface. Insert the applicator in the top of the docking station of the aerosol can, with the metal tip facing down. Do not push down on the applicator until ready to cool.
2. Push down on the applicator for 5 seconds. Then allow the can with the applicator to rest for 5 seconds. (Do not press for longer than directed and wait at least 5 minutes before reactivating.)
3. Remove the applicator from the aerosol can. Be careful to avoid contact with the metal tip.
4. Apply the metal tip on the wart for 20 seconds or less, depending on the size of the wart (see section 9). Make sure the metal tip covers as much of the wart as possible.
5. Wash hands (except treated area) immediately after use.
6. When used by more than one person and/or after each application, clean the applicator with alcohol on a small piece of cloth.

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.

6. INSTRUCTIONS FOR USE ON VERRUCCAS

1. Soak foot with verruca for 5 minutes in warm water. Dry thoroughly. File the verruca area with a pumice stone or pumice file (not included in the Acetocaustin Wart and Verruca Freeze Treatment packaging) before applying Acetocaustin Wart and Verruca Freeze Treatment.
2. Place the aerosol can on a hard surface. Insert the applicator in the top of the docking station of the aerosol can, with the metal tip facing down. Do not push down on the applicator until ready to cool.
3. Push down on the applicator for 5 seconds. Then allow the can to rest for 5 seconds. (Do not press for longer than directed and wait at least 5 minutes before reactivating.)
4. Remove the applicator from the aerosol can. Be careful to avoid contact with the metal tip.
5. Apply the metal tip on the verruca for 40 seconds or less depending on the size of the wart (see section 9). Make sure the metal tip covers as much of the verruca as possible.
6. Wash hands immediately after use.
7. When used by more than one person and/or after each application, clean the applicator with alcohol on a small piece of cloth.

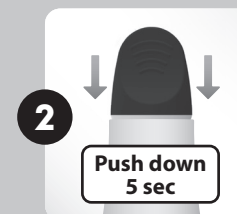
It is important that the instructions in the information leaflet are followed exactly. Careless use can cause freezing too deeply, causing permanent damage to the uppermost layer of the skin on fingers and toes. This may result in permanent scars or nerve damage.

Comfort pads (not included in the Acetocaustin Wart and Verruca Freeze Treatment packaging) can be used to protect the tender verruca area after treatment has been completed.

HOW TO USE ACETOCAUSTIN WART AND VERRUCA FREEZE TREATMENT



Place the aerosol can on a hard surface. Insert the applicator in the top of the docking station of the aerosol can, with the metal tip facing down. **Do not push down on the applicator until ready to cool.**



Push down on the applicator for 5 seconds. **Do not press for longer than directed and wait at least 5 minutes before reactivating.**



Allow the can with the applicator to rest for 5 seconds. Then remove the applicator from the aerosol can. Be careful to avoid contact with the metal tip.



Apply the metal tip on the wart for 20 seconds or verruca for 40 seconds. Make sure the metal tip covers as much of the wart or verruca as possible.



7. WARNINGS, LIMITATIONS & CAUTIONS

Read this important information carefully before you use the product and save it for future reference.

WARNINGS

- Keep out of reach of children. Children cannot understand the instructions to properly use this product. Content is hazardous if swallowed, inhaled, sprayed or exposed to heat. For external use only. Use only as directed. If Acetocaustin Wart and Verruca Freeze Treatment 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.
- Do not use if you cannot see clear enough to read the information on the container or in this information leaflet.
 - Do not press for longer than directed and wait at least 5 minutes before reactivating. Pressing the applicator longer than instructed may release excess product, which can appear as leakage due to disrupted balance of product and gas release.
 - Do not use on children under the age of 4 years. It is uncertain how Acetocaustin Wart and Verruca Freeze Treatment may affect the child's skin.
 - Avoid contact with healthy skin. Use on these areas may cause burns and permanent scarring of the skin.
 - Avoid contact with eyes. Contact with eyes may cause blindness. Do not rub or touch eyes with hands if Acetocaustin Wart and Verruca Freeze Treatment has been applied to them. If product gets into eyes, call medical help right away.
 - Do not use if you cannot clearly see the wart you are treating. If you mistakenly apply Acetocaustin Wart and Verruca Freeze Treatment on conditions that are not warts, it may cause serious burns and permanent scarring of the skin.
 - Do not swallow or inhale. The content is toxic and may cause serious internal damage. If swallowed, get medical help right away.
 - Do not breathe vapour/spray and use only in well-ventilated areas because it is uncertain how the vapour/spray will affect the lungs. Breathing vapour/spray may be toxic.
 - Keep away from fire or flame and from source of sparks or ignition. Do not smoke while using Acetocaustin Wart and Verruca Freeze Treatment. Exposure to the heat may cause the container to explode, causing serious injury.
 - Do not pierce or burn aerosol spray can, even after use. Protect from sunlight and do not expose to temperatures above 50°C (122°F). Store at room temperature away from heat. Exposure to the heat may cause the container to explode, causing serious injury.
 - Tip of the applicator contains nickel, users with a nickel allergy should carefully try to determine if an allergic reaction occurs before repeating multiple treatments.

LIMITATIONS

- 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 open wounds or 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 Acetocaustin Wart and Verruca Freeze Treatment will result in worsening of the condition and possible further infection. These conditions may not be a wart and should be examined by a doctor.
- Do not use on moles, birthmarks, warts with hair growing from them, genital warts (on penis or vaginal area), or warts on the face or mucous membranes (such as inside the mouth, nose, anus, genitals, lips, ears or near eyes). Use on these areas may cause burns and permanent scarring of the skin or blindness.
- Do not treat each wart with Acetocaustin Wart and Verruca Freeze Treatment more than three times in total as the

- treatment might not be effective and can cause burns and permanent scarring.
- 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.

If you are not sure, consult your doctor. If you treat a skin condition as a wart with Acetocaustin Wart and Verruca Freeze Treatment and it is not a wart, you delay proper treatment. This delay may lead to a more serious skin condition or disease.

CAUTIONS

- The product should not be used beyond the expiration date. The lot number and the expiration date appear on the bottom of the aerosol can as well as the outside of the outer packaging.
- When used by more than one person and/or after each application, clean the applicator with alcohol on a small piece of cloth. When not properly cleaned cross- contamination of the virus can occur.
- In most cases, only one treatment is needed for each wart. Warts are usually gone in two weeks after treatment with Acetocaustin Wart and Verruca Freeze Treatment. 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 Acetocaustin Wart and Verruca Freeze Treatment 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 verrucas, the aching/stinging feeling may last 24 hours. If discomfort or aching/stinging feeling continues beyond this time, a few hours for common warts and 24 hours for verrucas, contact 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.
- Inspect product carefully before each use. If the product appears damaged, stop using it and throw it away. Damaged product may leak gas.

CONTRAINDICATIONS:

- Do not use if you are diabetic or if you have poor blood circulation. Acetocaustin Wart and Verruca Freeze Treatment works by freezing the wart. The frozen area in diabetic patients and those with poor blood circulation may not heal as quick or completely.
- Do not use if you are pregnant or breast-feeding. It is uncertain how Acetocaustin Wart and Verruca Freeze Treatment may affect patients under these conditions.

SIDE EFFECTS

- The following side effects can occur when using the product:
- 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.

8. FOLLOW-UP TREATMENT

For each common wart, only one treatment is necessary in most cases. Verrucas may require more than one treatment. In two weeks after treatment with Acetocaustin Wart and Verruca Freeze Treatment, 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 Acetocaustin Wart and Verruca Freeze Treatment more than three times in total. Consult your doctor if three treatments have not led to improvement. Do not apply Acetocaustin Wart and Verruca Freeze Treatment 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.

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 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 centre 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.

Dispose of the packaging and used parts in accordance with the country-specific regulations.

HOW TO RECYCLE AEROSOLS: Ensure aerosols are completely empty before recycling. Do not pierce, crush or flatten aerosol cans. Detach any loose or easily removable parts, such as the lid, and dispose of them with the rest of your recycling. Note: the tip contains heavy metals and might need to be disposed as hazardous material as defined in your local legislation.

9. APPLICATION TIME

The following application times should be used as indication:

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

10. EXPLANATION OF SYMBOLS

The warning signs and symbols on the packaging and instructions for use are essential to ensure that you use this product safely and correctly and to protect you and others from injury. The symbols are explained in the table below:

Symbol	Explanation
	Symbol for the manufacturer
	Symbol for the distributor
	Symbol that indicates to consult the instructions for use
	Symbol that indicates that caution is necessary when operating the device
	Symbol for the expiration date
	Symbol that indicates that the item is a medical device
	Symbol that indicates the Unique Device Identifier
	Symbol for the Lot number
	Symbol that indicates that the product should be stored between 10°C and 25°C
	Symbol that indicates to keep the product away from sunlight
	Symbol that indicates the age limit for usage