Acetocaustin®
Skin Tag Treatment

PLEASE READ INSERT CAREFULLY BEFORE USING ACETOCAUSTIN SKIN TAG TREATMENT. WE ADVISE YOU TO KEEP THIS LEAFLET, YOU MAY NEED TO READ IT AGAIN.

1. CONTENTS OF ACETOCAUSTIN SKIN TAG FREEZE TREATMENT

A pressurized container 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 skin tag. 12 disposable foam discs.

2. BACKGROUND ON SKIN TAGS

A skin tag is a small, soft, piece of skin that may be raised from the skin and hang off the skin by a connecting stalk. They are usually similar in color to the surrounding skin.
Skin tags are considered to be harmless and are not contagious. They are usually found on the neck, chest, back, under the breasts, under the arms or in the groin area. They are most common in middle-aged and older adults, diabetics and overweight individuals. Skin tags usually don't cause any pain, however they can become irritated if something, such as clothing or jewelry rubs on them.
If you are unsure about whether you have a skin tag, please see your doctor.

3. WHAT IS ACETOCAUSTIN SKIN TAG FREEZE TREATMENT USED FOR?

Intended purpose: Acetocaustin Skin Tag Freeze Treatment is indicated for the over-the-counter treatment of skin tags, for patients aged 18 years and older.

Acetocaustin Skin Tag Freeze Treatment freezes the skin tag instantly using the same method as doctors worldwide. Freezing the skin tag destroys the tissue which should usually cause the skin tag to fall off within two weeks after 1 treatment. If the skin tag has not fallen off in 2 weeks, you may treat the skin tag again, up to three treatment cycles.

When the applicator is applied to the skin tag, the skin will turn white as a sign that it is being frozen. 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.

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 skin tag within a few days. You may not see this easily.

The frozen skin of the treated skin tag will fall off after about 10-14 days. In the meantime, new skin will have formed under the blister.

4. HOW DOES ACETOCAUSTIN SKIN TAG FREEZE TREATMENT WORK?

Acetocaustin Skin Tag Freeze Treatment freezes skin tags. The freezing destroys affected tissue. When the applicator is first cooled and then pressed (applied) on the skin tag, freezing begins within a few seconds and the skin will turn white. 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 may form (sometimes filled with blood) under the skin tag within a few days. You may not see this easily. The frozen skin of the treated skin tag 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 Skin Tag Freeze Treatment visit www.dryglo.com. For all product enquiries, please contact the distributor.

THEOTCLAB
Fred. Roeskestraat 115
1076 EE Amsterdam
The Netherlands

Distributor
Company name
Address 123456 City
Country

5. INSTRUCTIONS FOR USE

1. Apply the disposable foam disc with the adhesive side to the skin with the hole directly over the skin tag.
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. (Do not press for longer than directed and wait at least 5 minutes before reactivating).
4. Allow the can to rest for 5 seconds. Then remove the applicator from the aerosol can. Be careful to avoid contact with the metal tip.
5. Apply the metal tip on the skin tag for 40 seconds. Make sure the metal tip covers as much of the skin tag as possible. After application remove the foam disc and dispose of it. Do not re-use.
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. This may result in permanent scars or nerve damage.

6. FOLLOW-UP TREATMENT

For each skin tag, only one treatment is necessary in most cases. In two weeks after treatment with Acetocaustin Skin Tag Treatment, skin tags are usually gone. If a skin tag or part of it is still there two weeks after treatment, you may then safely treat it again.

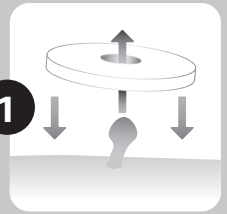
Do not treat each skin tag with Acetocaustin Skin Tag Freeze Treatment more than three times in total. Consult your doctor if three treatments have not led to improvement. Do not apply Acetocaustin Skin Tag Treatment together with any other method of skin tag removal because it is uncertain how the combination 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 skin tag 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 skin tag, 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 skin tag 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.

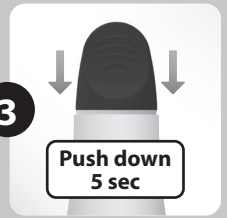
How to use Acetocaustin Skin Tag Freeze Treatment



Apply the disposable foam disc with the adhesive side to the skin with the hole directly over the skin tag.



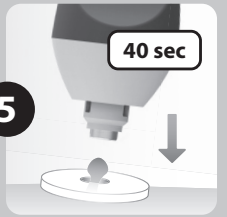
Place the aerosol can on a hard surface. Insert the applicator in the top of the docking station of the aerosol can, with the metal tip facing down.
Do not push down on the applicator until ready to cool.



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 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 skin tag for 40 seconds. Make sure the metal tip covers as much of the skin tag as possible. After application remove the foam disc and dispose of it. Do not re-use.

50ml MD 0482

7. WARNINGS, LIMITATIONS & CAUTIONS

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

WARNINGS

- 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.
- 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 Skin Tag 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 skin tags, 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 use under the age of 18. It is uncertain how Acetocaustin Skin Tag Freeze Treatment may affect the skin.
- Do not use if you cannot clearly see the skin tag you are treating. If you mistakenly apply Acetocaustin Skin Tag Freeze Treatment on conditions that are not skin tags, it may cause serious burns and permanent scarring of the 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.
- If product gets into eyes, call medical help right away.
- 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 Skin Tag 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 moles, birthmarks, warts with hair growing from them, genital warts (on penis or vaginal area), or skin tags 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.
- 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 Skin Tag Freeze Treatment will result in worsening of the condition and possible further infection. These conditions may not be a skin tag and should be examined by a doctor.
- Do not treat each skin tag with Acetocaustin Skin Tag Freeze Treatment more than three times in total as the treatment might not be effective and can cause burns and permanent scarring.
- If you are not sure, consult your doctor. If you treat a skin condition as a skin tag with Acetocaustin Skin Tag Freeze Treatment and it is not a skin tag, 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.
- If there is more than one skin tag, only treat one skin tag at a time. Treat each skin tag separately, with a two-week period between treatments.
- In most cases, only one treatment is needed for each skin tag. Skin tags are usually gone in two weeks after treatment with Acetocaustin Skin Tag Freeze Treatment. If a skin tag or a part of it is still there two weeks after treatment, you may then safely treat again.
- Do not treat each skin tag with Acetocaustin Skin Tag 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 skin tags should disappear within 24 hours after application. If discomfort or aching/stinging feeling continues beyond this time contact your doctor. This may mean that the area has been frozen too deeply and medical attention may be needed.
- Wash hands immediately after use.
- 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 Skin Tag Freeze Treatment works by freezing the skin tag. 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 Skin Tag Freeze Treatment may affect patients under these conditions.

8. 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 skin tag after a few days.

9. EXPLANATION OF SYMBOLS

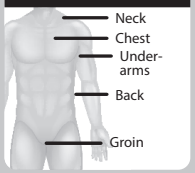
The warning signs and symbols on the packaging and instructions for use are essential to ensure that you use this product safely and correctly and to protect you and others from injury. The symbols are explained in the table below

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

Skin tag identifier

ONLY USE THIS PRODUCT IF YOUR SKIN TAG HAS ALL 4 CHARACTERISTICS SHOWN IN THE PICTURES BELOW.

LOCATION



Skin tags **MUST** be located in one of these 5 locations. Only treat skin tags if they are located on the neck, chest, underarms, back or groin.

SIZE

2mm - 6mm



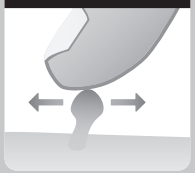
Skin tags **MUST** be 2mm to 6mm in size.

COLOR



Skin tags **MUST** be similar in color to the surrounding skin.

SHAPE/FEEL



Skin tags **MUST** be soft and flexible. You should be able to move them back and forth with your finger. They must also be raised above the skin by a stalk or stem-like piece of skin.

If your skin tag DOES NOT have ALL 4 characteristics, DO NOT USE this product. See a doctor as you may have a more serious skin condition.

Use **ONLY** as directed. Please consult instructions for use for additional warnings.