

TROSYD[®] wortie

Treatment for the removal of common and plantar warts

A. Indications

The Trosyd Wortie[®] wart removal treatment is an over-the-counter product for the treatment of common and plantar warts, intended for patients over 4 years of age.

B. Contents of the Trosyd Wortie treatment for the removal of warts from hands and feet

A pressurised can containing 50 ml of liquid compressed dimethyl ether gas, equipped with a metal tip to freeze the wart in a localised manner.

This leaflet describes the operation and methods of use of the product, in addition to detailing warnings and information on limitations of use.

C. Background information on warts

Common warts (also called "verruca vulgaris") frequently grow on fingers, the back of the hand, elbows, knees and upper part of the foot.

Common warts are recognized by their rough "mosaic-like" surface. The wart virus, which is extremely contagious, can be transmitted from person to person or from one part of the body to another through direct contact with the infected skin.

Plantar warts they are similar to the common ones, but only grow on the sole of the foot or under the toes. They are generally painful and often have the shape of a small circle of white skin with black dots in the middle. Plantar warts are also contagious and can be transmitted from person to person through contact with a damp or wet surface, such as the floor.

D. How Trosyd Wortie works

- Trosyd Wortie[®] freezes common and plantar warts. When the special cold applicator is pressed (applied) on the wart, the freezing actions begins in a few seconds and the skin turns white. Freezing produces a mild sensation of pain, tingling and/or burning. Once the applicator has been removed, the treated area resumes its initial colour and the pain/tingling/burning sensation quickly decreases, eventually disappearing within a few hours.
- A redness area as large as the frozen area may appear once the treated area has returned to its normal temperature and recovered its normal colour. In some cases, freezing may cause a blister (sometimes with blood inside) under the wart within a few days. The blister may not be visible.
- The frozen skin will peel off along with the treated wart after about 10-14 days. Meanwhile, a new layer of skin will grow under the vesicle.

Trosyd Wortie for the removal of warts has been compared with other cryotherapy products in order to evaluate its freezing strength. The results are visible in the images below.

Targeted freezing



Trosyd Wortie

Other brands

E. What you need to know before using Trosyd Wortie

- Do not use Trosyd Wortie on face, armpits, chest, moles or birthmarks, hairy warts, genital warts (on the penis or vaginal area), on mucous membranes (such as those in mouth, nose, anus, genitals, lips, ears, or near the eyes).
- Do not use Trosyd Wortie if you cannot clearly identify the wart to be treated
- Do not use Trosyd Wortie unless you can clearly read the information on the can or this leaflet.
- Do not use on children under the age of 4
- If used on children, for safety reasons, it must always be applied by adults.

F. How to use Trosyd Wortie

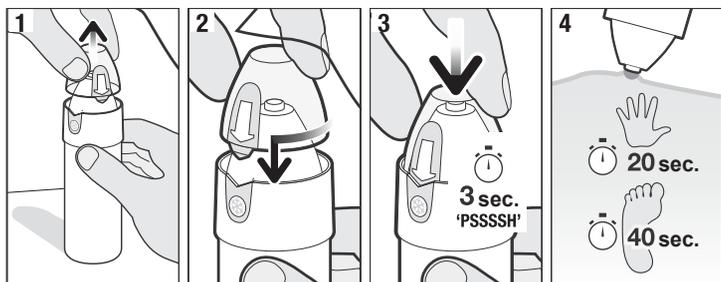
Apply Trosyd Wortie once on the wart, as indicated in Section G of the instructions

It is important to strictly follow the instructions contained in the package leaflet. Improper use can cause permanent damage to the skin, which can result in scarring or nerve damage due to excessive freezing or loss of liquefied gas.

- In most casts, a single wart treatment will suffice. If there is no improvement after three applications, consult your Primary Care physician
- After applying Trosyd Wortie, wait 14 days for the wart to fall off. If there are no changes to the wart within this period of time, you can apply Trosyd Wortie a second time.
- Always wait 14 days between applications.
- Clean the applicator after each application with a small cloth soaked in alcohol.
- After each application, allow the metal tip to reach room temperature before reactivating it for use on other warts.

G. Instructions for use

For safe and effective use, comply with the time directions in the instructions. We highly recommend that you use a timer on hand and read the instructions thoroughly before using Trosyd Wortie.



Clean the tip and put the cap back in the closed position; then wait 14 days for the wart to fall off.

For common and plantar warts

1. Remove the cap and place the can on a table or flat surface

Works in 1 application!

- Simple to use
- Does not damage the surrounding skin
- Suitable for children over 4 years old

2. Keep the can in vertical position; reposition the cap by aligning the arrow with the crystal symbol shown on the can.
3. Press the cap down for 3 seconds (**do not exceed 3 seconds**) You will hear the activation sound (hissing sound)
4. Apply the frozen metal tip precisely on the hand wart for 20 seconds, and for 40 seconds on the plantar wart.

H. Precautions

Do not use Trosyd Wortie if:

- The can was not placed on a flat surface during activation
- you do not hear the "hissing sound" during activation (release of aerosols) and/ or
- the "hissing sound" continues even after activation and/or
- the tip does not cool down after activation (a "frozen layer" must appear on the metal tip).

The correct functioning of the device is not guaranteed if one or more of the above conditions are not met. Device malfunction can cause injury or poor/partial treatment efficacy.

- Do not extend the application beyond the times indicated 20 seconds for common warts and 40 seconds for plantar warts. Do not exert excessive pressure when placing the applicator on the common or plantar wart.
- If there are multiple warts on your fingers or toes, treat them one at a time. Freezing more warts on a small area may delay the healing process, or the area may not heal adequately. Treat each remaining wart individually, with an interval of two weeks between treatments.
- The pain/burning sensation due to the treatment usually disappears after a few hours of application. If the discomfort or pain/burning sensation continues beyond this period, or if the pain is more intense than expected, consult your Primary Care physician.
- Do not apply Trosyd Wortie[®] together with other wart removal treatments, as the effects on the skin of combined use are not known.
- Do not inhale vapours/aerosols, use only in well ventilated areas. The inhalation of vapours/aerosols can have toxic effects.

I. What to do after treatment

- Keep the treated area clean.
- It is possible to swim and shower.
- Do not nick or scratch the treated area, as it could cause infections.
- If necessary, protect the blisters with a sterile gauze or plaster.
- Do not puncture the vesicles. The perforation of the vesicles is painful and can cause infections.
- Avoid sun exposure, or use only one protection (with SPF of or higher than 30); limit any possible trauma to treated areas much as possible, until complete healing (i.e., when the wart falls off and the skin returns to its normal colour).

J. What to do if you are not sure you have a wart

Use Trosyd Wortie[®] only you know you have a wart. If in doubt, consult your Primary Care physician. Applying Trosyd Wortie[®] on a skin growth that is not a wart may delay the appropriate treatment, which, in turn, can lead to the onset of a more serious skin disorder or disease. Read carefully "Warnings" and "Contraindications".

K. Side Effects

- Following application, the colour of the skin may change, ranging from white to red. A blister may form under the wart, and a pain/burning sensation is normal for a few hours. If this sensation lasts beyond 24 hours, or if any other problems occur (for example, frostbite outside the affected area or reduced sensitivity), contact your Primary Care physician as soon as possible. It is completely normal for the area to be more sensitive for a few days.
- After the wart has fallen off, you may experience skin de-pigmentation or minor scarring.
- After a few days, black dots may appear in the middle of the treated wart.
- The use of cryotherapy products for freezing warts can cause minor burn injuries due to low temperatures inherent in the freezing effect

L. CONTRAINDICATIONS

- Do not use in case of diabetes or circulatory insufficiency. Trosyd Wortie[®] works by freezing the wart: in subjects suffering from diabetes or circulatory problems, the area subjected to the freezing treatment could heal less quickly or only partially.
- Do not use if you are pregnant or breastfeeding.
- Do not use on irritated skin, or on infected, red or inflamed areas, as in the case of itching or swelling. It is possible that you may not have a wart; for additional information, please consult your Primary Care physician.

WARNINGS

Extremely flammable. Container under pressure. Do not pierce or burn the can even after use. Keep away from heat/sparks/open flames/incandescent surfaces. Do not smoke. Do not vaporise on open flames or other sources of ignition. Do not expose to temperatures higher than 50°C Protect the device from sunlight and store in a cool, dry place. Perforation of the container or its exposure to heat can cause it to explode, resulting in serious injuries. **Avoid contact with eyes.** Contact with eyes can cause blindness. Do not rub or touch your eyes after applying Trosyd Wortie[®] on your hands. In case of contact with eyes, rinse thoroughly with water for 15 minutes and seek immediate medical attention. **For external use only. Keep out of the children's reach.** Children are unable to understand the instructions on the correct use of this product.

Trosyd Wortie[®] for wart removal contains: Dimethylether

CE 0344

MEDICAL DEVICE

Last revision of this instruction leaflet: March 2020

The product can be used up to the expiration date indicated on the package and on the bottom of the pressurised can.

For additional information visit the site www.trosyd.it

Manufacturer:

Trimb Healthcare, Barbara Strozzilaan 201,
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Exclusive distributor:

Giuliani Spa
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PAP
Box and
instructions
Paper
Sorted recycling.
Check the provisions
in force
in your municipality.