



Treatment for the removal of common and plantar warts

A. Indications for use

Trosyd® Wortie® *Solution + Patches* is a medical device indicated for the treatment of common (hands) and plantar (feet) warts.

Trosyd® Wortie® *Solution + Patches* is indicated for adults and children from 4 years of age.

B. Background information on warts

Warts known as “common” or “vulgaris” are small skin growths caused by the human papilloma virus (HPV), which is highly contagious and can be transmitted from person to person or from one place on the body to other through direct contact with the infected area. Warts often develop on the fingers, the back of the hands, knees, or elbows. They are easily recognisable by their typical “cauliflower-like” appearance.

Plantar warts occur on the soles or under the toes. Generally painful, they often appear as a small white skin circle with black dots in the middle. Plantar warts are also contagious and can be spread from person to person through contact with a damp or wet surface, such as the floor.

Common and plantar warts are traditionally treated in two ways. The first requires the use of acid-based solutions, such as Trosyd® Wortie® *Solution + Patches*, which break and destroy the wart. The second method consists in the physical destruction of the wart by laser or freezing by cryotherapy, as in the case of Trosyd® Wortie®, a medical device which, like Trosyd® Wortie® *Solution + Patches* does not require a medical prescription.

C. What makes Trosyd® Wortie® *Solution + Patches* different from other products on the market?

The unique composition of the ingredients selected on the basis of published scientific data, makes Trosyd® Wortie® *Solution + Patches* effective and less aggressive on the skin. The solution dries quickly on the skin and, thanks to a very precise applicator brush, avoids damaging any surrounding healthy skin. The clear patch covers the wart after applying the solution, thus ensuring that the liquid remains on the application site and protects the treated area.

D. How does Trosyd® Wortie® *Solution + Patches* work?

GTA Technology (Glycolic Acid + Trichloroacetic Acid + Denatured Alcohol) is unique and exclusive to Trosyd® Wortie® *Solution + Patches*, and was conceived on the basis of the most recent studies conducted on the treatment of common and plantar warts. These works have been studied by a team of expert doctors, who have transferred them into an innovative and fast application product.

• Combination of effective and safe ingredients

The Trosyd® Wortie® *Solution + Patches* formula consists of a mix of acids known for their effectiveness in the treatment of common and plantar warts. This combination of components allows Trosyd® Wortie® *Solution + Patches* to work effectively and to be less aggressive on the skin.

The Trosyd® Wortie® *Solution + Patches* formula performs a dual action: 1. It removes the superficial layers of the wart and softens any hardened skin, thus allowing the wart to fall off (active ingredient: Glycolic acid).

2. It chemically peels off the wart tissues (active ingredient: Trichloroacetic acid).

• Quick and precise application

Trosyd® Wortie® *Solution + Patches* dries quickly in about 30 seconds, avoiding discolouration or skin irritation. The fine dispensing brush avoids damaging the surrounding healthy skin.

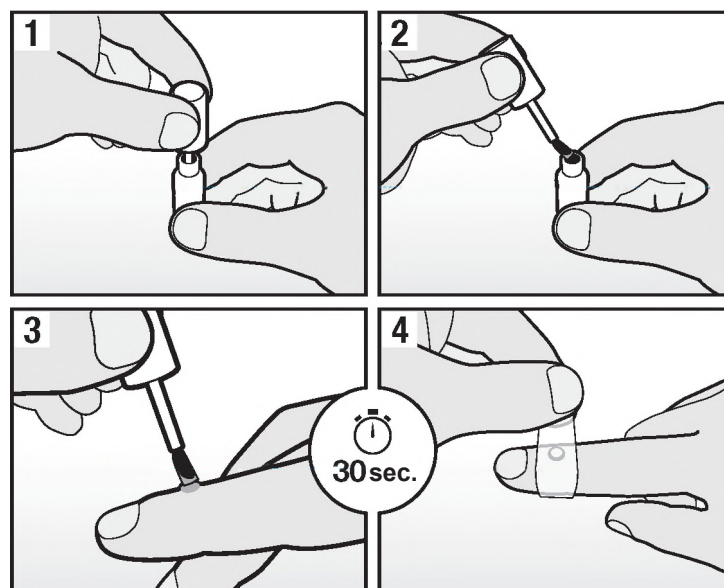
- Unique 2-ingredient mix
- Does not burn
- Dries in a few seconds
- Only 2 applications per week
- Suitable for children over 4 years old

• Clear protective patches

Trosyd® Wortie® *Solution + Patches* contains patches suitable for covering any treated area after application. The patches allow a longer exposure of the wart to the active ingredients. In addition, the patches function as a protective layer that helps the treated area stay clean and protected, avoid contact with the wart and, as a result, alleviate any discomfort and reduce the chances of contagion.

E. How to use Trosyd® Wortie® *Solution + Patches*?

Wash the treatment area with warm water and soap. Make sure that the skin is dry before application.



Place the bottle of Trosyd® Wortie® *Solution + Patches* on a flat surface (for example, the sink surface) in order to avoid accidental spills.

1. Use the Trosyd® Wortie® *Solution + Patch* applicator brush to carefully apply a thin layer of the solution on the wart. Avoid applying the solution on the surrounding skin and, in case of accidental contact with the skin, remove the solution with a tissue or cloth. If necessary, wash the entire area again with warm soapy water and then reapply the product.
2. Let dry. About 30 seconds are enough.
3. Once the application area is completely dry, apply the clear patch to the wart.
4. Leave the patch in place for at least 4 hours, or until it wart begins to peel off on its own. If the patch is still on the wart after 24 hours, carefully remove the patch and wash the area with warm water and soap.
5. Apply the product 2 times a week as recommended, until the wart has completely disappeared.

The duration of treatment may vary based on the size of the wart. While some warts disappear after 1 week of treatment, larger warts can take up to 8 weeks of treatment.

It is important to accurately follow the instructions provided in this information leaflet. Improper use of the product can cause minor burns or skin irritation, or cause permanent damage to the outermost layer of the skin.

F. Warnings:

- Follow the instructions carefully.
- Apply the solution only on the wart to be treated.

- Make sure you do not apply the solution to the healthy skin around the wart.
- Do not use on areas of the body with thin or sensitive skin, such as face, armpits, breasts, buttocks or genital area. Use in these areas could cause irritation and/or leave scars.
- Do not use this product if you cannot clearly see the wart you want to treat; contact someone who can clearly see the wart and, therefore, apply the product correctly.
- Do not use Trosyd® Wortie® *Solution + Patches* in case of hypersensitivity to one or more of its ingredients.
- Do not use on children under the age of 4.
- Do not use on irritated skin or any area of the body that is infected, red, or shows any signs of inflammation, such as itching or swelling.
- Treating these areas with Trosyd® Wortie® *Solution + Patches* may worsen the condition. In fact, your condition may not be a wart; for this reason, it is necessary to consult your doctor. Treating a problem other than the wart with Trosyd® Wortie® *Solution + Patches* means that healing can be delayed and any delay may lead to more a complex condition.
- Do not use on skin spots, moles, birthmarks, hair-covered warts, genital warts (on the penis or vaginal area) or warts on the face or mucous membranes (such as, in mouth, nose, anus, genital area, on the lips, ears or near the eyes). Use in these areas could cause permanent burns and scars, or lead to blindness if brought into contact with the eyes.
- Disposable non-reusable patches.
- Do not use if you are unable to read the information on the bottle, or this information leaflet carefully.
- Do not use Trosyd® Wortie® *Solution + Patches* with other remedies indicated for the removal of warts because the resulting combination of effects is unknown.
- Do not use the product if you are pregnant, breastfeeding, have diabetes or circulatory failure.
- Avoid contact with eyes. Do not touch or rub your eyes with your hands if they have been treated with Trosyd® Wortie® *Solution + Patches*. If the product accidentally gets into your eyes, rinse immediately and for 15 minutes, then seek prompt medical advice.
- Do not swallow it. The content is toxic and could cause serious internal damage. If accidentally swallowed, immediately seek medical advice or contact the Poison Control Centre.
- For external use only. If Trosyd® Wortie® *Solution + Patches* is not used exactly as instructed, or if it is accidentally applied directly to the skin or any wart-free areas, it could cause irritation and scarring.
- Keep out of the children's reach. Do not allow children to use the product without supervision. The product contents may be hazardous if swallowed or used in parts of the body other than warts. Choking Hazard - Contains small parts.
- Flammable. Keep away from heat/sparks/open flames/hot surfaces. Store in a cool and dry place, at room temperature and away from heat sources.

G. Precautions

- Glycolic acid and Trichloroacetic acid are corrosive. Apply only on the wart, avoiding any surrounding areas.
- Avoid exposing the treated area to UV rays and direct sunlight in order to avoid irritation and hyperpigmentation. Using the protective patch will help protect the treated area.
- Clothes, jewellery, furniture or upholstery may be damaged if they come in contact with Trosyd® Wortie® *Solution + Patches*
- In case of inflammation or acute pain and inflammation after application, stop the treatment, wash the area carefully with soap and water to remove any product from the skin and consult your doctor or trusted pharmacist.

- If persistent redness or inflammation is experienced after one or more treatments, discontinue treatment and consult your Primary Care physician.
- Using an excessive dose of product can cause irritation.
- Pay close attention during application.
- Trosyd® Wortie® *Solution + Patches* can be applied by an adult on children from 4 years of age.
- Consult your doctor if you do not notice any improvement after 3 months of consecutive application.
- The product should be used by one person only, in order to maintain the maximum possible hygiene conditions.

H. Possible side effects:

Like other remedies for the removal of warts, Trosyd® Wortie® *Solution + Patches* can cause side effects, which however do not occur in every subject treated.

- While the product is working, it is possible to feel a slight tingling or burning and/or soreness of the treated area. Generally these side effects are just temporary, and only in rare cases may a skin spot (darkening or redness of the skin) appear.
- Immediately stop the treatment and inform your doctor or pharmacist if your symptoms worsen or if the discomfort increases.
- Protect the treatment area from direct exposure to the sun and UV rays to avoid irritation and hyperpigmentation. Using the patch will help protect the treated area.

I. What to do after treatment

- Keep the treated area clean.
- Swimming or showering is permitted.
- Do not nick or scratch the treated area, as infections could arise.
- Avoid exposing the treated area to sunlight.

J. Package Contents of Trosyd® Wortie® *Solution + Patches*

1. One bottle contains 5ml of solution. The solution is sufficient for 18 applications, which cover the entire treatment cycle.
2. 18 protective, clear and disposable patches to cover and protect the wart after applying the solution.

This information leaflet contains information about product indications, as well as warnings and restrictions.

Trosyd® Wortie® *Solution + Patches*. Ingredients: Denatured Alcohol, Glycolic Acid, Trichloroacetic Acid.

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The product can be used up to the expiration date shown on the box and on the label.

For more information visit the website www.trosyd.it

Manufacturer:

Trimb Healthcare,
Barbara Strozziiaan 201,
1083 HN Amsterdam,
The Netherlands

Exclusive distributor:

Giuliani Spa
Via P. Palagi, 2,
20129 - Milan
Italy

Trosyd® Wortie® offers two different types of treatment for the removal of common and plantar warts, both indicated for adults and children from 4 years of age:

Trosyd® Wortie® Cryotherapy - Single application - no direct contact between gas and skin.

Trosyd® Wortie® *Solution + Patches* Solution with applicator brush and protective patches - only 2 applications per week - dries quickly.