Instructions for use HeltiQ Wart Freezer

EN

- For external use only -
- Only intended for use to remove warts on hands and feet -

Before use, carefully read the instructions for use. Use the product only as directed. Not using the product as directed could cause frostbite.

Do not use if dispenser or packaging is damaged.

CONTENT HELTIQ WART FREEZER

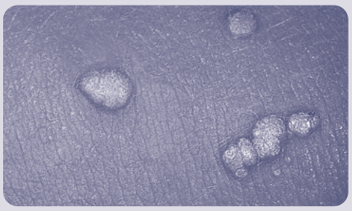

1 38 ml dispenser with permanently fixed applicator cap; contains Dimethyl ether (DME)
1 instruction for use
8 protective plasters
16 cleansing swabs

PRODUCT DESCRIPTION

HeltiQ Wart Freezer is a cryosurgical product for treatment of common and plantar warts on hands and feet. They can be removed by freezing (cryotherapy).

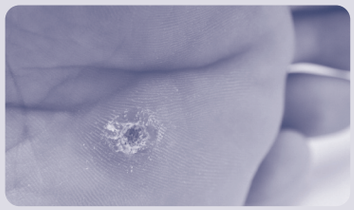
IDENTIFYING COMMON AND PLANTAR WARTS

COMMON WARTS



Warts are skin growths on the top layer of skin that are caused by a virus called the human papilloma virus (HPV). Common warts usually appear on the back of the hands and near fingernails; they may also appear on elbows and knees.
Common warts are
- Usually rough, hard and have a 'cauliflower-like' dome-shaped appearance
- Not usually painful

PLANTAR WARTS



Plantar warts occur on the bottom or the soles of the feet. They sometimes have visible dark specks beneath the surface of the wart. The pressure of standing and walking flattens and forces a plantar wart beneath the skin's surface forming a tough 'callus-like' skin over the wart.
Plantar warts
- Can be painful, especially if located on heel or ball of the foot
- Dome-shaped appearance which can be flattened through standing/walking

If there is doubt whether the condition is a wart, consult a medical professional.

INDICATIONS / INTENDED USE

The product is indicated for the removal of cutaneous warts on hands and feet.
The product is intended for use as an over-the-counter product (OTC) for individuals older than 4 years of age.

CONTRAINDICATIONS

The HeltiQ Wart Freezer is contraindicated for the following:
- When there is or has been a confirmed diagnosis of cancer and/or treatment for cancer
- For use in treatment of genital warts
- For dark or highly pigmented skin
- For birthmarks, (hairy) moles, beauty spots or any other strange looking outgrowths
- For skin that is irritated or inflamed or when eczema is present
- For use in the face
- For sensitive skin areas i.e., neck, armpits, breasts and buttocks
- For unknown skin conditions or when there is doubt that the skin condition is a wart
- When there is hypersensitivity or allergy to extreme cold (cold type urticaria)
- For diabetics and individuals with circulatory problems (Raynaud's disease)
- For individuals are taking immunosuppressive medicines or when there is a confirmed diagnosis for autoimmune or collagen diseases
- For use when there is HIV infection
- For individuals on anticoagulation medication and Haemophilics
- For use on children under 4 years of age
- In combination with other wart treatments

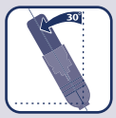
WARNINGS/PRECAUTIONS

- Extremely flammable dispenser. Pressurized dispenser. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources
- No smoking
- For external use only
- Do not pierce or burn, even after use
- Do not spray on an open flame or other incendiary source
- Do not expose the dispenser to temperatures exceeding 50 °C
- Keep out of reach of children
- Do not inhale the spray
- Avoid contact with the eyes. Do not spray into the eyes as it can cause frostbite and blindness
- Do not repeat the treatment more than 4 times with 14-days intervals between treatments.
  Consult a medical professional if the wart is not removed
- Product may cause frostbite, de-pigmentation or scar formation when the product is not used in accordance with these instructions for use
- Consult a medical professional, if pregnant or breastfeeding

DIRECTIONS FOR USE COMMON AND PLANTAR WARTS

Precaution! Do not remove the permanently fixed applicator cap from the dispenser.

Position the wart upwards. Place the round opening of the applicator cap directly over the wart so it encircles the wart. Ensure the edges of the applicator are in close and snug contact with the surrounding skin.



Hold the aerosol dispenser vertical at maximum a 30° angle for the treatment to be effective.

Hold the product firmly over the wart. Press the bottom of the dispenser firmly with the thumb **3x**.

Hold the applicator in place for **10 seconds** before removing it from the skin. A 2 mm white halo could appear. A small scar will appear when the site is dry, which will heal in the coming days and weeks.

Precaution! If there is a group warts located close together, treat each wart separately at an interval of 14 days between treatments.

Precaution! In most cases a single treatment will be sufficient to remove the wart. For persistent warts repeat the treatment after **10 seconds**.

Should the wart not be removed within 14 days, repeat the treatment as directed in this instruction for use.

Remove the applicator cap from the wart. A slight temporary skin sensitivity or tingling may be felt immediately after treatment.

Clean the opening of the applicator cap with a cleansing swab after each use to reduce the risk of transmission or infection.

If the wart is elevated and/or very sensitive after the treatment, protect the wart with one of more of the protective plasters.

AFTER THE TREATMENT

- The treatment may cause blistering. When that happens, do not puncture the blister
- Do not pick at or scratch the site or wart that has been treated
- Keep the treated area dry and clean to avoid infection
- Swim, wash, bath and shower as normal

STORAGE CONDITIONS

- Store in a cool and dry area. Do not exceed 25 °C
- Dispose of contents/container in accordance with local regulations

POTENTIAL SIDE EFFECTS

- The cryotherapy process may cause hypopigmentation (light patches) or hyperpigmentation (dark patches) to occur. This will disappear
- Bleeding
- Blistering
- Scarring when freeze application is applied longer than directed
- Temporary discomfort such as pain or tingling
- Consult a medical professional in case of infection and/or complications

COMPLAINTS AND CUSTOMER SERVICE SUPPORT

Any serious adverse event related to this product must be declared to Koninklijke Utermöhlen NV, distributor and national health authority in your country. Contact Koninklijke Utermöhlen NV and distributor with any questions or to report problems.

Utermöhlen
Since 1880

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140016 - 740184 - V3.20211119

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