



Instructions for use HeltiQ Skin Tags

- For external use only -

- Only intended for use to remove skin tags on individuals older than 18 years -

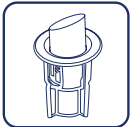


Before use, carefully read the instructions for use. Use the product only as directed. Not using the product as directed could cause frostbite.



Do not use if dispenser or packaging is damaged.

CONTENT HELTIQ SKIN TAGS



- 1 38 ml dispenser with permanently fixed applicator cap; contains Dimethyl ether (DME)
- 1 instruction for use
- 8 protective plasters
- 8 foam-tips

PRODUCT DESCRIPTION

HeltiQ Skin Tags is a cryosurgical product for treatment of skin tags located under the arms, in the neck/throat area or under the breasts. They can be removed by freezing (cryotherapy).

IDENTIFYING SKIN TAGS

Skin tags are also known as acrochordons and occur frequently in both men and women and are benign. Skin tags are non-contagious. They occur spontaneously. A skin tag has the following characteristics: skin colored, soft and painless, moves easily, protrudes and has a small stem.

INDICATIONS/INTENDED USE

The product is indicated for the removal of skin tags from neck/throat, under the arms, under the breasts. The product is intended for use as an over-the-counter product (OTC) for individuals older than 18 years of age.

CONTRAINDICATIONS

HeltiQ Skin Tags is contraindicated for the following:

- When there is or has been a confirmed diagnosis of cancer and/or treatment for cancer
- When skin tags are larger than 4 mm. Large skin tags are not treatable with this method
- When the colour of the skin tag differs from the colour of the surrounding skin
- For skin tags located on buttocks and anal genital area
- When skin is heavily pigmented or on dark pigmented skin
- When skin tag is hairy or contains hair
- When skin tag is hard or bleeds
- For skin that is irritated, infected or sensitive
- When there is hypersensitivity or allergy to extreme cold (cold type urticaria)
- For diabetics and individuals with circulatory problems (Raynaud's disease)
- For individuals that 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 Haemophilic
- For use on children under 18 years of age
- In combination with other treatments for skin tags

WARNINGS AND 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 treat a skin tag more than 4 times within a treatment interval of 14 days. Consult a medical professional if the skin tag 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



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DIRECTIONS FOR USE

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



Place a protective plaster around the skin tag to be treated.



Place a foam tip holder in the opening at the top of the applicator cap. Press the holder gently into the opening.

Precaution! The foam tips provided are single use disposable; They are not for reuse. For each skin tag to be treated use a new foam tip. Do not touch the surface of the used foam tip.



Press the bottom of the dispenser firmly with the thumb 4-times to saturate the foam-tip. Wait 10 seconds to let foam-tip reach temperature.

Precaution! Do not place the foam tip on the skin tag.

Precaution! Hold the dispenser away from the body. Do not point in the direction of individuals



Gently hold the foam tip against the skin tag for 40 seconds.

Precaution! In case of multiple skin tags located close together, treat each skin tag separately with an interval of 1 day between treatments.



Remove the protective plaster surrounding the skin tag directly after the treatment.



Carefully remove the foam-tip from the applicator cap opening by pulling it out by its holder.

Precaution! Keep the foam tip away from other skin surfaces. Contact with the used foam tip surface could result in freezing of the skin surface.

Precaution! Should the skin tag not be removed within 14 days, repeat the treatment. Do not treat a skin tag more than 4 times within a treatment interval of 14 days. Consult a medical professional, should the treatment not have the desired effect.

AFTER THE TREATMENT

- The treatment may cause blistering. When that happens, do not puncture the blister
- Do not pick at or scratch the site 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 (darkpatches) 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.



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