

Instructions for Use (IFU)

Read these instructions carefully before use. Keep this leaflet with the device; you may need to read it again.

EndWarts® FREEZE

1. INTRODUCTION

EndWarts FREEZE is a rapid home treatment that effectively removes warts on hands, arms and feet. Through an Ultra Freeze Technology™ it freezes the wart at -80°C allowing the deepest layer of the wart to be reached.

EndWarts FREEZE is quick and easy to use.

EndWarts FREEZE is suitable for adults and children over 4 years old.

2. WHAT YOU NEED TO KNOW BEFORE AND AFTER TREATMENT

Do not use EndWarts FREEZE:

- on children under 4 years of age
- on the face, groin, genitals, scalp or mucosa
- on healthy skin (skin without warts)
- on warts located on sensitive skin - take care when treating areas of thin skin (e.g. around joints)
- if the wart and/or surrounding skin is bleeding or open, irritated, itchy, infected or red
- if you are not sure the growth is a common wart, consult your doctor or pharmacist before use
- on moles, corns, blisters, other skin defects or anything that might be skin cancer (melanoma)
- on liquid filled vesicles on the skin (called 'molluscum contagiosum') or any other vesicles or blisters
- if you are diabetic or have blood circulation or blood clotting problems
- on multiple warts at a time; on warts in a cluster or warts that are closer than 3 cm. Treat one wart and wait 14 days before treating the next wart
- if you are pregnant or breast-feeding, check with your doctor or pharmacist whether you should use this product

Safety precautions:

- Do not inhale. For external use only. Keep out of reach of children.
- If inhaled: remove person to fresh air and keep comfortable for breathing.
- May cause drowsiness or dizziness.
- Do not apply for longer than 15 seconds on thin skin (hands, fingers, toes, top/side of feet and arms), or for 40 seconds on thick, callous skin (soles of feet). Excessive or incorrect application can cause pain and skin or nerve damage.
- EndWarts FREEZE should be used by an adult when treating warts on children.
- Nitrous oxide is a non-toxic, non-flammable gas, but it will support combustion in case of fire. Keep away from clothing/heat/sparks/open flames/hot surfaces. Do not smoke or use close to a naked flame. Use in a well-ventilated place.
- Pressurised container. May burst if heated. Do not pierce or burn the cartridge even after use - the device is under high pressure and cannot be opened.
- Call a Poisons Information Centre (phone 13 11 26 (Australia) or 0800 764 766 (New Zealand)) or your doctor if you feel unwell after using this product.

For best results on plantar warts (on the soles of the feet)

Hard skin on top of the wart makes freezing more difficult. For best results on plantar warts:



- Soak the affected area in lukewarm water until the skin is soft.
- Gently remove any overlaying skin on inward growing warts on the foot (e.g. with a single use nail file (emery board) disposed of after use).
- Make sure that the wart and surrounding skin are completely dry before treatment.

- Do not file the wart itself; it may become tender and will form a new hard surface.

After using EndWarts FREEZE

Using EndWarts FREEZE may cause a tingling feeling and the skin may feel sore or irritated. These effects should disappear after a few hours. Immediately after treatment the treated area will turn white. After a little while the skin will go back to its normal colour and the wart will look red.

Within a few minutes to several days after freezing, a blister can develop, occasionally filled with blood. This is a normal result of the freezing process and usually indicates that the treatment has been successful. Do not attempt to burst the blister. If necessary, protect it with a sterile bandage, or if the blister has opened, disinfect it properly.

The treated wart will slowly disappear after 10 to 14 days. If the wart, or part of it, does not disappear within 14 days you need to repeat the treatment (steps 1, 2 and 3). The skin may take longer to fully recover.

If the wart is located on the sole of the foot, it may feel painful to walk on it. To make it less painful, apply a round non-medicated corn plaster to the area.

- Do not pick at the treated area or try to tear the wart off!
- Keep the treated area clean and disinfect if needed. This is important to avoid infection.
- Bathing and showering can occur immediately after treatment. Pat dry the treated area afterwards.

Do I need to repeat the treatment?

EndWarts FREEZE is efficient – the core of the wart will be reached quickly and will be destroyed because of the cold temperature. One treatment may be sufficient. Old or large warts may need more than one treatment, especially if they are on the soles of your feet.

Consult your doctor:

- if you or your child experience any unexpected side effects
- if the wart does not heal
- if the wart has not disappeared after 3 treatments.

3. POSSIBLE SIDE EFFECTS

Possible side effects include:

- Blisters (possible blood blisters) around the treated area - which varies from case to case (see Section 2 - What You Need to Know Before and After Treatment: After using EndWarts FREEZE).
- The skin losing its colour - called "depigmentation".
- Minor burns and scar formation.
- Skin/nerve damage (in case of overexposure).
- Transient disturbed sensation (tingling, prickling feeling).

If any of the side effects become serious or you notice any that are not listed in this leaflet, tell your doctor or pharmacist.

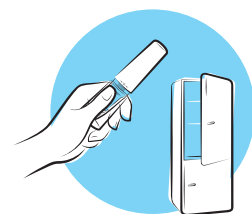
4. HOW TO STORE ENDWARTS FREEZE

Before first use:

- Store in a dry and cool place (below 25°C). Protect from light.
- Do not store in the freezer.
- Do not expose the device to temperatures above 50°C.
- Do not store in cars, caravans, or other places that heat up. An increase in temperature will damage the device and disable it permanently.

After each use:

- Wait two minutes after use, discard the disposable tip and attach a new tip.



- Place the cap on and store in the refrigerator.
- Do not store in the freezer.
- Do not expose the activated device to temperatures above 35°C, as this will activate a safety feature that disables the device permanently.

- If you clean the plastic parts of the device, use a damp cloth only.

5. OTHER INFORMATION

Packaging and expiry date:

- The package includes one EndWarts FREEZE device, 7 disposable tips and one Instructions for Use.
- When loaded for 2 seconds before application, the device is sufficient for up to 7 doses.
- Do not use the product after the expiry date shown on the pack.
- Once activated, the shelf life of the product when stored in the refrigerator is 2 months.
- Dispose of the empty product by returning it to your local pharmacy.

What to do if the device is empty or broken:

- If you do not see frost or ice vapour after a successful activation and loading of the device (see section 6 - How to Use ENDWARTS FREEZE) it has run out of gas and a new EndWarts FREEZE should be used.
- If there is a continuous hissing sound after you have activated the product and all the gas runs out, the device is broken. Do not try to open or repair it yourself, even if you think it is empty - return the product to your pharmacy.

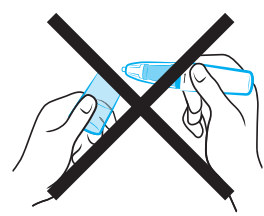
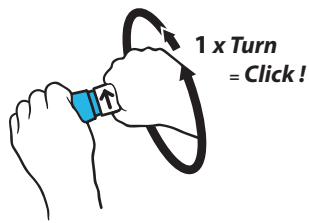
6. HOW TO USE ENDWARTS FREEZE

BEFORE YOU START THE TREATMENT READ THE FOLLOWING STEPS

ACTIVATE

Before the very first use only

EndWarts FREEZE needs to be activated once. Do not remove the cap yet.



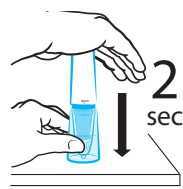
Turn the white part of the device a minimum one full turn in the direction of the arrow until you notice a loud click. Some force is needed.

After you have activated the device, this step does not need to be repeated.

1

LOAD

Before each treatment, EndWarts FREEZE needs to be loaded with cold gas.

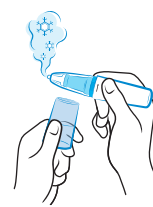


Place EndWarts FREEZE upright on a table, with the transparent cap facing down. Hold the device with a steady grip. With the other hand, push the white part of the device downward for exactly 2 seconds.

Pushing for longer will waste useful doses. Pushing it shorter, reduces the freeze effect.

2

CHECK



Remove the transparent cap and use the product immediately. Check that you see ice vapour. If not, repeat step 1.

3

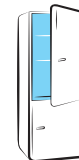
TREAT



Press the tip firmly against the wart.

For safe use and best results – the application time is crucial.

15 seconds on thin skin (hands, fingers, toes, side/top of feet and arms)
40 seconds on thick, callous skin (soles of feet).



Wait two minutes after use, discard the disposable tip and attach a new tip.

Place the cap on and store in the refrigerator (store for no longer than 2 months; mark it on the calendar). The wart will slowly disappear after 10 to 14 days. If the wart, or part of it, does not disappear within 14 days you need to repeat the treatment (steps 1, 2 and 3). The skin may take longer to fully recover. If, after three treatments, the wart is still there, consult your doctor.



Warning



Danger
(compressed air)



May cause or intensify fire

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