Cod. LG00836/14 del 20-11-2017

8874

UK

DIZIONE

VIETATA LA MANOMISSIONE - RENDERE DOPO L'USO

VENDITA

DIM. MIN. FON

8 pt

Ū	Verifica Qui
	le misure di
1	stampa
2 -	Check Here
	of print
3	³ w 5 3 cm
	0 1 2 3

FILE DIGITALE DI PROPRIETÀ DELLA ROTTAPHARM S.p.A.

PROSPETTO

ISTELLA

CYAN

Instructions for use (IFU)

Read the instructions carefully before use. Keep this Instruction for use; you may need to read it again.

[III] Mylan

2

COLORI:

EndWarts. **EFFECTIVELY REMOVES WARTS**

1. INTRODUCTION

EndWarts FREEZE is a rapid home treatment that effectively removes warts on hands, arms and feet. It is the first home treatment with nitrous oxide, a very cold gas. Through an Ultra Freeze Technology[™] it freezes the wart at -80°C and reaches the deepest layer of the wart.

EndWarts FREEZE starts off at a very low temperature (-80°C) that remains during application. EndWarts FREEZE is by far the coldest home freeze treatment, which is shown in an in-vitro temperature test including several freeze devices for home treatment. EndWarts FREEZE is therefore more efficient.

EndWarts FREEZE is a high tech device that is quick and easy to use. The treatment 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 and take particular 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 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 pregnant or a nursing mother
- on persons with diabetes and/or problems with blood circulation or blood clotting
- on multiple warts at the same time, if they are located close together. Wait 14 days before you treat the next wart.

Safety precautions

- Do not inhale. For external use only. Keep out of the sight and reach of children.
- Do not apply for longer than 15 seconds on hands and arms, or 40 seconds on 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 heat/sparks/ open flames/hot surfaces. Do not smoke or use close to a naked flame.
- · Pressurized 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.

For best results on foot warts

BODOTTO

270 x 545 MM

NERO

ENDWARTS FREEZE

Hard skin on top of the wart makes freezing more difficult. For best result on foot 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 with e.g. a foot file.

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 will cause a tingling feeling and the skin may feel sore or irritated. These effects should go away 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 was 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. However, it may take longer for the skin 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 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.
- Bathing and showering is allowed immediately after treatment.

Do I need to repeat the treatment?

EndWarts FREEZE is very efficient- after just a few seconds of use, the core of the wart will be reached and destroyed because of the cold temperature. Normally, only one treatment is sufficient. Old or large warts may need more than one treatment, especially if they are under the soles of your feet.

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 and steps 2, 3 and 4. See 6. HOW TO USE ENDWARTS FREEZE

If a wart does not go away after 3 treatments, consult your doctor.

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, 'After using EndWarts FREEZE'.
- The skin losing its colour- called "depigmentation".
- Minor burns and scar formation.
- Risk of skin/nerve damage (in case of overexposure).
- Transient disturbed sensation (tingling, prickling feeling).

4. HOW TO STORE ENDWARTS FREEZE

Before first use

- Store in a dry and cool place (between 5 25°C). Protect from sunlight.
- Do not store in the freezer.
- Do not expose 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



- Put the cap on and store in the refrigerator - this will give EndWarts FREEZE a longer shelf life and increase the number of useful doses.
- 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.
- Wait two minutes after use, discard the disposable tip and insert a new tip. EndWarts FREEZE is now ready for the next use.
- If you clean the plastic parts of the device, use a damp cloth only.

5. OTHER INFORMATION

Packaging and expiry date

- One package includes one EndWarts FREEZE cartridge (7,5g nitrous oxide liq.), a set of 6 disposable tips and one Instruction for use.
- Shelf life in the refrigerator after activation: 2 months.
- Do not use the product after the expiry date shown on the pack.
- Dispose the empty product according to current regulations on disposal of urban waste.

What to do if the device is empty or broken:

4

- If you do not see frost or ice vapour after a successful activation and loading of the device (see 6. HOW TO USE ENDWARTS FREEZE) it has run out of gas - use a new EndWarts FREEZE.
- If there is a continuous hiss 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 STEPS 1 TO 4





Before the very first use only

ACTIVATE

EndWarts FREEZE needs to be activated once



Turn the white part of the device minimum one full turn in the direction of the arrow until the star is back in the shaded zone. Some force is needed.

Don't worry if you turn the star past the shaded zone.

After you have activated the device successfully, never repeat step 1.



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



Place EndWarts FREEZE upright on a table with the transparent part down. Hold the device with a steady grip. With the other hand, push the white part of the device downward for **exactly 2 seconds**. You will hear a hissing sound.

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





Check that you see ice vapour. If there is no ice vapour, repeat step 2.



Press the tip firmly against the wart.

For best results - the time is crucial!

- 15 seconds on hands, fingers and arms
- 40 seconds on feet

Put the cap back on. DONE!

After use, store in a refrigerator.



The wart will slowly disappear after 10 to 14 days. If the wart, or part of it, does not disappear within 14 days repeat steps 2, 3 and 4.

Distributeur : Mylan Products Limited 20 Station Close, Potters Bar, Hertfordshire, EN6 1TL www.endwarts.uk



1627/620352/17G/07020505/0





Remove the transparent cap and use the product immediately!