

Read the instructions carefully before use. Keep the instructions for use. You may need to read it again. For external use only.

Keep out of the sight and reach of children.

- 1. What EndWarts PEN is and what it is used for

## EndWarts, PEN

#### 1. WHAT ENDWARTS PEN IS AND WHAT IT IS USED FOR

EndWarts PEN is an effective solution for the removal of warts and verrucas. The solution should be used for the treatment of warts and verrucas on hands, feet, elbows and knees, for both children and adults. The unique formula in EndWarts PEN helps the body to dry out and reject warts/verrucas.

EndWarts PEN is absorbed directly into the wart/verruca and the solution leaves no trace on the skin. You can, for example, put on socks or take a bath immediately following application.

EndWarts PEN is a Swedish patented and CE marked Medical Device which is biodegradable. The solution is bactericidal and when used correctly, does not scar or cause infections. The content of EndWarts PEN is sufficient for about 30 treatments.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE ENDWARTS PEN

#### 2.1 DO NOT USE ENDWARTS PEN

- · Do not apply on facial warts, genital warts, molluscum, birthmarks, corns, hard skin or other skin defects. In case of uncertainty of the diagnosis contact your doctor.
- Do not cover the wart/verruca with a plaster following treatment with EndWarts PEN. Use of a plaster after treatment may cause skin damage, see 4. POSSIBLE SIDE EFFECTS.
- Do not use if the wart/verruca being treated becomes tender, bleeds or the skin becomes irritated. Pause treatment until the skin has
- Do not combine EndWarts PEN with other wart/verruca removal
- Do not use EndWarts PEN if you are allergic to any of the ingredients listed in 5. STORAGE AND OTHER INFORMATION.

#### 2.2 WARNINGS AND PRECAUTIONS

EndWarts PEN is corrosive with an irritating and



strong smell. Do not inhale. For external use only. Keep out of the sight and reach of children

Do not over apply! Excessive or incorrect application can cause pain and skin damage, see 4. POSSIBLE SIDE

EFFECTS.

- If you use too much or accidentally spread the solution on the surrounding skin, rinse immediately with plenty of water to reduce skin
- If the solution gets into your eyes, rinse immediately and repeatedly with lukewarm water for a minimum of 15 minutes and seek medical

Take particular care when treating sensitive areas of thin skin, for example on small children and on top of the hand, see 3.1 DOSAGE AND APPLI-CATION and 3.2 TREATING CHILDREN.

Do not tamper with the pen (do not open, cut nor pierce).

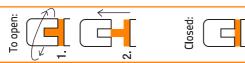
#### 3. HOW TO USE ENDWARTS PEN

#### 3.1 DOSAGE AND APPLICATION

Only a minute amount of the EndWarts PEN is needed in order to be effective. Read the instructions below carefully, as the solution is corrosive. To avoid getting the solution on the surrounding skin, be cautious and hold the pen with a firm grip when applying the solution. Replace the cap correctly after use.

The pen delivers a very small amount of colourless solution when the tip is pressed on the wart/verruca. The pen can be experienced as dry. The pen is designed so that only the amount of solution required to treat the wart/ verruca will come out. To demonstrate that the pen works, put the tip of the pen against a paper. You will see a moist mark on the paper. You will also notice an acrid smell of the product when you remove the cap.

Illustration 1



To open, the cap is rotated until the orange strip on the pen is in line with the small cavity on the cap. Once in line, the cap can be safely pulled off the body of the pen. To close the cap, push it back tightly and rotate to locked position. See illustration  ${\bf 1}$  above.



Proceed with the application:

- Press the tip of the pen lightly against the wart/verruca and paint the wart or verruca surface with the solution
- Apply on the wart/verruca only, covering all of the wart/verruca (illustration  $\boldsymbol{A})$ - For large wart/verruca — tilt the pen (Illustration  $B)\,$
- Apply for three seconds
- Do not apply on healthy skin
- Treat **regularly** once a week until the wart/verruca has completely disappeared. Illustration A Illustration B





When treating warts/verrucas on thin skin (like on the top of hands/ **feet/fingers**), a single application every second or third week may be sufficient. For larger, older warts/verrucas, plantar warts/verrucas and warts/

verrucas with a thick skin layer, a more frequent application can be tried. If the wart/verruca is not regressing on once a week treatment, treat

twice a week, or every other day as long as the skin is not irritated. DO NOT OVER APPLY - treat strictly for up to three seconds and only on the wart/verruca.

If you feel burning or note an irritation (skin becomes red, tingling, stinging), stop the treatment and see 4. POSSIBLE SIDE EFFECTS. Do not start treatment again until irritation is gone.

If the product does not work on the wart/verruca, please consult your Specialist. If treating several warts/verrucas, start by treating a select number

for two weeks to see how the the skin reacts. If the skin is unaffected, continue with the remaining warts/verrucas.

Keep the wart/verruca soft between treatments by using normal skin lotion or oil. The wart/verruca remnants can then come out more easily.

In the beginning of the treatment, the wart/verruca may turn white and initially grow outwards, before it starts to dry out. When the wart/ verruca expands, the surrounding skin may become tender. Take care that there is no overlying skin on the wart/verruca, see below.

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If the wart/verruca feels tender, or if it throbs, this can be because you have applied too much solution, see 2.1 DO NOT USE ENDWARTS PEN, or the wart/verruca cannot emerge through the overlying skin. If the skin is covering the wart/verruca, then an opening needs to be made in the skin, for example, by using a tweezers, to release the wart/verruca. If you have an old or hard wart/verruca, moisten it before treatment by soaking the affected area in warm water until the skin is soft. Pinch or scrape the skin on top of the wart/verruca, by using for example tweezers. For thick skin on inward-growing verrucas remove the hard skin carefully. For cuticle warts/verrucas you may have to pierce a tiny hole in the outermost skin to enable the solution to reach through to the wart/ verruca. Do not file the warts/verrucas without medical recommendation. The warts/verrucas may become tender and they will form a new hard surface.

After a few treatments black spots are usually seen in the wart/ verruca. These are tiny blood capillaries that supply the wart/verruca with blood. This is a sign that the wart/verruca is about to disappear and treatment should be continued until the black spots and the wart/ verruca have entirely disappeared. Sometimes the black spots can bleed a little if you have scratched the wart/verruca. Wait a few minutes until the bleeding stops before applying the solution, otherwise it can sting a bit. If it stings, rinse with cold water immediately to soothe the pain.

#### **3.2 TREATING CHILDREN**

For children, adults should always apply the treatment. Follow 3.1 DOSAGE AND APPLICATION carefully as the solution is corrosive. Small children have soft, thin skin. Use EndWarts PEN solution very sparingly on children's warts/verrucas. The warts/verrucas usually disappear after 2-3 treatments.

Children under 4 years of age can be treated with the EndWarts PEN but always ensure that it actually is a wart/verruca and not any other kind of skin defect. Consult your General Practitioner or paediatrician before treating. For children under 4 years of age, it is particularly important to evaluate the location of treatment (children have soft, thin skin) and reduce the dose. Treat less frequently, such as every second or third week.

- Press the pen lightly on the wart/verruca once for three seconds and paint the wart/verruca surface with the solution.
- Be careful not to touch the surrounding skin.
- If the child tends to suck the area where the wart/verruca is present, you can wash the treated area with water. The solution has already penetrated the wart/verruca.
- If it burns or stings when treating, rinse the wart/verruca with cold water and do not apply any more solution. It has already penetrated the wart/verruca.

If the child feels burning or note an irritation (skin becomes red, tingling, stinging), stop the treatment and see 4. POSSIBLE SIDE EFFECT. Pause the treatment and do not start again until irritation is gone.

#### **3.3 TREATMENT OF PEOPLE WITH DIABETES**

People with diabetes should only use EndWarts PEN on warts/verrucas on healthy skin (undamaged and unaffected by diabetic disease) and with extra care. In the event of problems, always consult your doctor/ nurse or foot care specialist.

## 3.4 HOW LONG SHOULD ENDWARTS PEN BE USED FOR

EndWarts PEN is very effective - most warts/verrucas disappear and do not return. Sometimes warts/verrucas already present beneath the skin can emerge when you start the treatment.

The warts/verrucas can look very different and the time required to remove them can therefore vary; commonly 5 to 15 treatments. It can also take shorter or longer time. Factors that affect duration of treatment of warts/verrucas include: age, type of wart/verruca, your immune system, location of wart/verruca and how long the wart/verruca has been present. Reduced immune defence and medication, e.g. cortisone, are factors that can prolong the treatment duration. New warts/verrucas are normally easier to remove than older ones. Children's warts/verrucas are usually easier to remove than those on adults. For inward-growing verrucas and cuticle warts, which have been present for many years, it may take a longer duration before you notice the treatment having an effect and it takes significantly longer for the wart/verruca to completely disappear.

## 3.5 WHEN SHOULD I STOP USING ENDWARTS PEN

Stop using EndWarts PEN when there are no black spots visible (tiny blood capillaries that supply the wart/verruca with blood) or if the wart/ verruca has fallen out, shrivelled or there is a "hollow" where the wart/verruca was. The skin returns to normal afterwards. If you continue the treatment for too long after the wart/verruca has gone, the skin turns pink and a little watery. In such an event, STOP using EndWarts PEN immediately. After a few weeks, check where the wart/verruca was located; if you see a small dot it might indicate wart/verruca remnants. If that is the case, you will need to retreat with EndWarts PEN.

## 3.6 PREGNANCY AND BREASTFEEDING

There are no known risks in pregnant and/or breastfeeding women.

## 4. POSSIBLE SIDE EFFECTS

EndWarts PEN contains a strong acid. If the solution is over applied or applied incorrectly, it can cause skin damage, see 2.1 DO NOT USE ENDWARTS PEN. Follow the instructions in 3.1 DOSAGE AND APPLI-CATION to avoid skin damage.

Temporary side effects can occur on the application site, for example tenderness, stinging, pain, redness, burning sensation or bleeding from blood capillaries. Pause treatment until the skin is completely recovered.

Over application and incorrect application can result in more severe side effects such as blisters, wounds, dark pigmentation of skin, chemical burns, inflammation, tissue death (necrosis) or scarring. The damaged area should be kept clean to avoid infection. Stop the treatment in such instances and in the case of serious skin damage, contact a doctor.

EndWarts PEN has a strong smell that can be irritating to respiratory organs and eyes. Do not smell the contents of the pen. Side effects may include irritation in the respiratory system and/or throat. Side effects may also include runny nose, runny eyes or difficulty in breathing.

Isolated cases of allergic reaction such as redness, rash and itching have been reported.

## 5. STORAGE AND OTHER INFORMATION

Storage: Keep out of the sight and reach of children. Store between 15 and 25  $^{\circ}\mathrm{C},$  preferably upright with cap facing down.

Contents: Formic acid, water, glycerol.

Packaging: Pen applicator with cap and instructions for use. The cap has a two-step opening function, see 3.1 DOSAGE AND APPLICATION.

Shelf life: See expiration date on the pen and the carton. Use up to 6 months after opening.

These instructions for use were last revised December 2019.

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



# 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<sup>TM</sup> 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

## 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

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 • Plieters (possible blood blisters) around the treat

- Blisters (possible blood blisters) around the treated area which varies from case to case, see Section 2, 'After using EndWarts FREEZE'.
- $\bullet\,$  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.
- $\bullet\,$  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:

- 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



## ACTIVATE

Before the very first use only

**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.



## LOAD

**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



Remove the transparent cap and **use the product immediately!** 

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



TREAT



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.

After use, store in a refrigerator.

DONE!



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.