

INSTRUCTIONS FOR USE



Corrosive

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
2. What you need to know before you use EndWarts PEN
3. How to use EndWarts PEN
4. Possible side effects
5. Storage and other information

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 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/verruca. 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.
- Do not use a plaster with EndWarts PEN. Use of a plaster during 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 recovered.
- Do not combine EndWarts PEN with other wart/verruca removal treatments.
- 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 damage.
- If the solution gets into **your eyes**, rinse immediately and repeatedly with lukewarm water for a minimum of 15 minutes and seek medical attention.

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

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

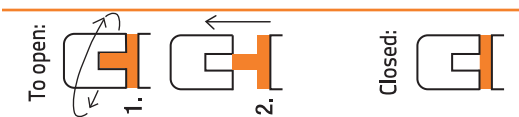
3. HOW TO USE ENDWARTS PEN

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. The pen can be experienced as dry. The pen is designed so that only the needed amount of the solution to treat the wart 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 1 above.



Press the tip of the pen lightly against the wart for one second and repeat once. Be careful not to apply the solution to the surrounding skin.

Warts can be of different sizes and therefore you need to angle the pen tip depending on the size of the wart. If the wart is small, use the tip of the pen (illustration A). If the wart is larger you may need more solution. Press the tip of the pen against the wart for one second. Repeat twice. You can angle the pen so that the flat or round surface of the pen is used (illustrations B and C).

Illustration A

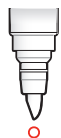


Illustration B



Illustration C



For a successful result, treat **regularly** once a week until the wart/verruca has completely disappeared, otherwise the process stops. If treatment is irregular, the whole process takes longer.

Old and/or large warts/verrucas on adults may after 4–5 treatments be treated every fifth day, if the skin is not irritated. **Do not over apply.**

When treating warts/verruca on **thin skin**, fewer applications may sometimes be sufficient. Treat less frequently, such as every second or third week.

If treating **several warts/verruca**s, start by treating a select number for two weeks to see how the skin reacts. If the skin is unaffected, continue with the remaining warts/verruca.

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.

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 a tweezers. For thick skin on inward-growing verrucas remove the hard skin carefully. For cuticle warts you may have to pierce a tiny hole in the outermost skin to enable the solution to reach through to the wart. Do not file the warts/verruca. The warts/verruca 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/verruca. The warts/verruca 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 reduce the dose. Treat less frequently, such as every second or third week.

- Press lightly with the tip of the pen **once** for one second.
- 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.
- 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.

3.3 TREATMENT OF PEOPLE WITH DIABETES

People with diabetes should only use EndWarts PEN on warts/verruca 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/verruca disappear and do not return. Sometimes warts/verruca already present beneath the skin can emerge when you start the treatment.

The warts/verruca 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/verruca include age, type of wart, your immune system, location of wart 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/verruca are normally easier to remove than older ones. Children's warts/verruca 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 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 APPLICATION 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 °C, preferably upright with cap facing down.

Contents: Colourless to slightly brown solution (formic acid, water, glycerol, lemon oil).

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 January 2017.

Printproof

ATTENTION!

We need an approved proof before we can start the production.

Please fill in this form in clear writing.

Date: 06-02-2018 **Proof no.: 1**
Order no.: 343336
Product Code: 130608_30WP.MED.IE.UK.I.04 MB
Article no. Dobber: D00261
Size: 210 x 450 mm **DOBBER HEALTHCARE LEAFLETS**
Folded: 210 x 25 mm
Print color(s) Dobber Healthcare Leaflets BV
Front: Black ■ + PMS 485 ■ + PMS 151 ■ Westerwerf 13
Back: - 1911 JA Uitgeest
Square (oversteek): - Phone +31 (0)251 31 19 50
Optical code: - E-mail: info@dobberpharma.com
Pharma code: - www.dobberpharma.com
Font: -
Font size: -
Leading: -

To be filled in by client

Approved: YES NO

Date:

Name and signature:

(This form belongs to SOP 'Werkzaamheden DTP-Studio'.)



APPROVATO

Da Vanessa Pileggi alle 13.00 , 06/02/2018

Ril op 105 mm