

PACKAGE LEAFLET: INFORMATION FOR THE USER



Bazuka Advance Treatment Pen contains a corrosive agent. [13] IMPORTANT: Read these instructions carefully prior to use. Keep this leaflet. You may need to read it again. Ask your

doctor, pharmacist or nurse if you need more information or advice. \triangle For use on the skin only. \clubsuit Keep out of the sight and reach of children.

In this leaflet:

- What Bazuka Advance Treatment Pen is and what it is used for
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 Treatment Pen

1. WHAT BAZUKA ADVANCE TREATMENT PEN IS AND WHAT IT IS USED FOR

Bazuka Advance Treatment Pen is a medical device indicated for the treatment of warts and verrucas found on the feet, hands, body, arms and legs. It is suitable for use by **adults** and children from 8 years old.

• Warts and verrucas are small excessive growths in the skin caused by the human papilloma virus (HPV). Warts often occur on the fingers, or on the back of the hands. You can recognise the common wart by the rough 'cauliflower-like' appearance of the surface. Verrucas occur only on the sole of the foot. They can be painful, and often look like a small white ring of skin with black dots in the centre. The virus is very infectious. This means that warts and verrucas can grow and spread, particularly if left untreated. The virus can also be transferred to other parts of the body or from one person to another.

HOW BAZUKA ADVANCE TREATMENT PEN WORKS -

Bazuka Advance Treatment Pen is specifically designed for topical administration directly onto warts and verrucas. The pen contains formic acid, which dries out the infected skin, thereby treating the wart or verruca. The pen is designed to deliver a safe amount of product and as a result may appear dry. On application, the treatment may not be visible as it is immediately absorbed into the wart or verruca.

2. BEFORE YOU USE BAZUKA ADVANCE TREATMENT PEN

Do not use Bazuka Advance Treatment Pen if you are known to be **allergic** (hypersensitive) to any of the ingredients listed in Section 6, **or bee/ant stings**.

- Do not use on children under the age of 8 years.
- Do not use the treatment pen if you have diabetes or suffer from poor blood circulation (peripheral vascular disease) to your hands or feet.
- Do not use the treatment pen anywhere near your face, armpits, breasts, bottom or genital (sex) area.
- Do not use on "warts" with hair growing from them, facial warts, birthmarks, moles, pigmented skin or any other spots. If you are unsure whether you have a wart or verruca that is suitable for treatment with Bazuka Advance Treatment Pen, ask your doctor, pharmacist or nurse before starting treatment.
- Do not apply Bazuka Advance Treatment Pen to sore or bleeding warts, irritated, inflamed, blistered or damaged skin. Wait until the skin has recovered.
- Do not use in combination with other wart removal therapies.
- Try to avoid unnecessary exposure to sunlight as this may cause temporary discolouration (either darkening or lightening) of the treated skin.
- Do not cover the treated area with a plaster. Use of a plaster after treatment may cause skin damage.
- · Do not shake the pen.
- · Always open the pen horizontally over a sink.
- Do not inhale and apply the treatment in a wellventilated space.

Take special care when using this product, it contains a corrosive agent with a strong smell.

Apply the treatment **carefully**, to the wart or verruca **only**. You should apply the product for the minimum time appropriate for your condition as outlined in Section 3 of this leaflet:

- Take care not to apply the treatment to surrounding healthy skin, especially on young children's delicate skin, because, when applied incorrectly or excessively, the treatment can result in blisters, inflammation, tissue damage, scars, burns or other wounds.
- When used on children, for safety reasons, it must always be applied by an adult.
- When applying to difficult to reach places the treatment should always be applied by another adult.
- There are no specific known risks for pregnant or breastfeeding women, however, it is recommended to consult your doctor, pharmacist or nurse prior to use.
- IF THE PRODUCT ACCIDENTALLY COMES INTO CONTACT WITH THE EYES OR MUCOUS MEMBRANES, RINSE IMMEDIATELY WITH PLENTY OF WATER FOR 15 MINUTES AND SEEK MEDICAL ADVICE.

Continued overleaf

3. HOW TO USE BAZUKA ADVANCE TREATMENT PEN

Bazuka Advance Treatment Pen delivers a small amount of colourless formulation, which may not be visible upon application to the skin. **Do not shake the pen** because this may damage it, causing it to leak. The pen is designed to deliver a safe amount of product and as a result may appear dry. To test the product, hold the tip against a piece of absorbent paper to confirm there is moisture present. The pen tip is not designed to deliver visible liquid drops.

It is important to apply the treatment initially for short contact times. The precise number of seconds required depends on the size, age and location of the wart or verruca you are treating. It is better to apply too little treatment initially, if in doubt.

To use Bazuka Advance Treatment Pen, follow the steps outlined below every other day (on days 1, 3 and 5) followed by 2 days' rest. Use only on warts and verrucas, on sites for which it is recommended. Carry on using the treatment pen in this way until the wart or verruca disappears or for a maximum of 6 weeks. Do not exceed the frequency or number of recommended applications or the maximum contact time.

- A. It is recommended to soak the affected area in lukewarm water for at least 5 minutes to soften the skin prior to treatment.
- B. If the wart or verruca is covered by hard skin, gently rub the hard skin off the surface of the wart or verruca, taking care not to break the skin. Take care not to file the wart or verruca itself.
- **C.** Open the pen carefully: always open the pen horizontally over a sink.
- D. Remove the cap of the pen by pressing down and turning counter clockwise.
- E. Gently stroke the wart with the tip of the treatment pen for the appropriate contact time (as per the guidance below). The treatment penetrates immediately. Make sure to treat the whole wart or verruca but take care not to touch the surrounding healthy skin with the pen.
- F. Recap the pen firmly after application.
- G. Wash your hands after touching warts or verrucas.
- H. Store the pen in its original packaging with the pen lid downwards.

On first use, be cautious as only a small amount of treatment is required. Start by treating a single wart or verruca for 1 second to see how the skin reacts. If the skin is unaffected and the treatment is well tolerated, then increase the treatment contact time using the information below as a guide:

- For younger children (ages 8 to 11 years), those with delicate skin, for small warts or verrucas, start cautiously and conservatively and increase the treatment contact time to a maximum of 10 seconds.
- For larger warts or stubborn verrucas on the sole of the feet, increase the treatment contact time to a maximum of 20 seconds.

Should any discomfort or pain occur, stop application. If it burns, stings or if the treatment is accidentally applied to healthy skin, rinse with cold water.

4. POSSIBLE SIDE EFFECTS

It is important to use the product as instructed. Do not use excessively as this can cause skin damage.

- A mild tingling or burning sensation can, in some cases, be felt for 10 to 15 minutes after treatment.
- If used on healthy skin, transient side effects can occur, such as stinging, irritation, redness, pain or bleeding.
 Stop treatment until the skin has fully recovered and keep the area clean to avoid possible infection.
- There may be a transient change to the pigmentation in treated skin which is exposed to the sun.
- This product has a strong smell. It may cause irritation to the respiratory system, throat and/or the eyes. Do not smell the contents of the pen directly as this may cause side effects such as a runny nose, runny eyes or difficulty in breathing.

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the Manufacturer and via the MHRA Yellow Card Scheme at: www.mhra.gov.uk/ yellowcard.

5. STORAGE

Store between 2 and 25°C and out of direct sunlight. Keep in the original packaging, with the pen lid downwards and out of the sight and reach of children. Do not use after the expiry date. Always recap the pen firmly after use.

Dispose of the product safely once no longer required.

6. FURTHER INFORMATION ABOUT BAZUKA ADVANCE TREATMENT PEN

Ingredients: Formic acid (85%), dimethyl isosorbide, aqua.

The pack contents:

- a treatment pen containing 3 ml of liquid (sufficient for minimum of 220 applications).
- this information leaflet which you must read carefully prior to use.

(4) Single patient - multiple use

Bazuka™ Advance Treatment Pen is classified and registered as a CE marked Medical Device Class IIa.

Manufacturer: Unigroup ApS, Diplomvej 373, DK-2800 Lyngby, Denmark.

UK Responsible Person: CMC Medical Devices Limited, Office 32, 19-21 Crawford Street, London, W1H 1PJ, UK.

Distributor: Diomed Developments Limited, Hitchin, Herts, SG4 7QR, UK. 'Bazuka' is a Registered Trademark of Diomed Developments.

This leaflet was last revised in December 2024

Find out more about warts and verrucas and Bazuka products at: www.bazuka.co.uk

For LOT and expiry date see base of carton or base of the pen.

