



A 'freezing' verruca and wart removal device based on the cryotherapy method used by doctors
Contains 12 applications

Please read all of this leaflet carefully, and familiarise yourself with the correct assembly and operation of the freeze device before you use it.

Keep this leaflet. You may need to read it again.

Ask your doctor, pharmacist or nurse if you need more information or advice.

In this leaflet:

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1. WHAT BAZUKA SUB-ZERO IS AND WHAT IT IS USED FOR

- Bazuka Sub-Zero is a home use 'freeze' treatment for **warts and verrucas on the hands and feet** based on the cryotherapy method used by doctors.
 - Warts and verrucas are benign skin outgrowths with a rough surface caused by the human papilloma virus (HPV). They are transmitted through direct contact with the infected area. The virus is very infectious. This means that warts and verrucas can grow and spread from one part of the body to another, particularly if left untreated. The virus can also be transferred from one person to another. There are many different types of warts but the most common are:

Common warts which have a rough 'cauliflower-like' appearance on the surface. They are often found on the hands and fingers but can appear anywhere.

Verrucas, also known as plantar warts, often look like a small white ring of skin with a black dot in the centre. They occur only on the sole of the foot, toes or heel. Due to the pressure caused by the weight of the body, the wart is flattened and pushed into the skin of the foot, causing pain and discomfort.

IF YOU ARE NOT SURE THAT THE OUTGROWTH ON YOUR SKIN IS A WART OR VERRUCA, CONSULT YOUR DOCTOR, NURSE OR PHARMACIST BEFORE USING BAZUKA SUB-ZERO.

HOW BAZUKA SUB-ZERO WORKS – Bazuka Sub-Zero quickly freezes the wart or verruca to its core. The area of skin that comes into contact with the frozen foam becomes white and a temporary slight burning, painful sensation may be felt. This is absolutely normal. After treatment a small, invisible blister will form at the root of the wart or verruca, helping it to loosen and fall off, often within a couple of weeks or so of freezing, revealing new, healthy skin underneath.

TREATMENT SUITED FOR THE DIFFERENT TYPES OF WARTS – Common warts: a single treatment is usually sufficient. If necessary, repeat treatment after 2 weeks. If the condition persists after 4 treatments consult a doctor. Verrucas are usually more resistant and it may be necessary to repeat the treatment 3-4 times, at fortnightly intervals. If the condition persists after 4 treatments, consult a doctor. Cluster of warts: it is advisable to treat each wart separately, at fortnightly intervals.

- Bazuka Sub-Zero is **generally suitable for adults, the elderly and children at least 4 years old. However, because it works by freezing, it is important to bear in mind that:**
 - the freezing procedure will cause a painful, aching or stinging sensation that can take a few hours to fade;
 - if used on children, for safety reasons it must always be applied by an adult, and;
 - if used by the elderly, or those with physical disabilities, the assistance of a helper may be advisable.
- This freezing kit comprises:
- an aerosol can containing a freezing agent and fitted with a hollow spout (in which to insert a disposable foam applicator);
 - 12 disposable foam applicators, for up to 12 freeze applications;
 - a special dome-shaped safety cap, imprinted with ON and OFF on opposite sides, which is used to 'charge' the foam applicator with the freezing agent (see Section 3), and;
 - this instruction leaflet – **which you must read carefully in order to familiarise yourself with the correct assembly and operation of the freeze device, before you use it.**

2. BEFORE YOU USE BAZUKA SUB-ZERO

Do not use Bazuka Sub-Zero:

- on children under the age of 4 years;
- if you have diabetes or circulation disorders. If you suffer from circulation disorders, consult your doctor before using this treatment;
- during pregnancy or when breast-feeding;

- on irritated or infected skin. If you have any doubts about the area to be treated, consult your doctor before application.
- on skin with dark spots, birthmarks, beauty spots, warts with hairs growing from them, or any other spots;
- anywhere on or near your face, armpits, breasts, bottom or genital (sex) area; or
- at the same time as any other wart or verruca treatment.

Taking medicines

This product is not known to affect, or to be affected by, any medicines that you may be taking. It must not be used, however, at the same time as other wart or verruca treatments.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

3. HOW TO USE BAZUKA SUB-ZERO TO FREEZE YOUR WART OR VERRUCA

Read all the indications provided on the information leaflet carefully before use and keep for reference.

- Use only to freeze individual warts and verrucas on sites for which it is recommended.
- Before freezing, to make verrucas (also known as plantar warts) more susceptible to treatment, soak the foot in hot water for at least 6 minutes then, after drying, file the callous layer of the verruca with an emery board or pumice stone to optimise the Bazuka Sub-Zero treatment.
- If you have several warts or verrucas located close to one another, freeze them separately, one at a time, at fortnightly intervals.
- When freezing warts or verrucas on the back of the hands or on the top of the feet and toes, be especially careful not to freeze for too long, and wiggle the fingers or toes gently during freezing.
- For some warts you should only need to freeze them once. However, old or large warts and verrucas on the heel or ball of the foot are more difficult to get rid of, so may need more than one freeze with Bazuka Sub-Zero;
 - if more than one freeze is required, leave 2 weeks before repeating the treatment;
 - do not freeze the same wart or verruca more than 4 times in total;
- Use each foam applicator only once.

Freeze only for very short contact times

- It is very important that you only freeze the wart or verruca for a matter of seconds.
- The precise number of seconds required depends on the size and location of the wart or verruca you are treating;
 - Larger warts take a little longer to freeze to the core;
 - Verrucas on the sole of the feet take slightly longer to freeze because they are deeper in the skin, particularly if they are located on the weight-bearing areas such as the heel and ball of the foot where the skin tends to be much thicker.
- Keeping these factors in mind, refer to the table below to help you choose the most appropriate contact time to use.

Determine your freeze contact time using this table		
For young children (e.g. ages 4 to 11) and/or those with delicate skin, a shorter contact time, of half the recommended number of seconds, may be advisable.		
Lesion Diameter	WART Contact Time	VERRUCA Contact Time
Small: less than 2.5 mm	10 seconds	For verrucas on the toes and instep (see shaded area on diagram) use same contact time as shown for warts, determined according to verruca size. For verrucas on heel and ball of foot (see white area on diagram), contact time can be increased up to a maximum of twice the corresponding time shown for warts – i.e. depending on size, up to a maximum of between 20 and 40 seconds.
Medium sized: from 2.5 mm to 5 mm	15 seconds	
Large: larger than 5 mm	20 seconds	

■ Area max. 20 sec.
□ Area max. 40 sec.

How to assemble the device and make it ready for freezing

Each time you use Bazuka Sub-Zero to freeze a wart or verruca, you will need to assemble the device, and then 'charge' the foam applicator with the freezing agent.

Assemble it as follows:

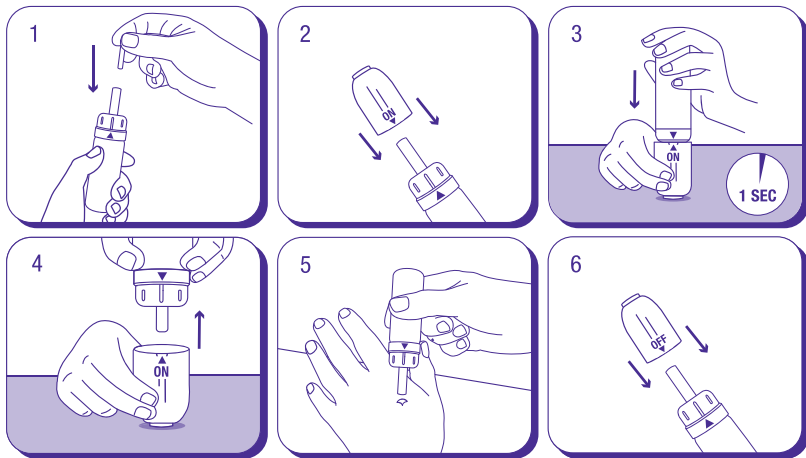
- a). Insert a foam applicator inside the tip of the hollow spout on the aerosol can. When properly inserted, half of the foam should be left sticking out of the spout.

'Charge' the foam applicator with the freezing agent, and use it to treat the wart or verruca as follows:

- b). Hold the can in a vertical position and place the safety cap over the dispenser.
NOTE: the cap is fitted with an ON-OFF safety device that enables activation in the ON position only.
To activate the dispenser, line up the arrow on the dispenser's plastic base with the vertical line marked ON on the safety cap.
- c). **THE CAN MUST BE TURNED UPSIDE DOWN TO ACTIVATE THE DEVICE**
Turn the device (i.e., the can with the cap and foam applicator inserted) upside down with the activator cap resting on a firm surface.
- d). Charge the foam applicator by holding the cap securely with one hand and pressing down firmly on the dome-shaped safety cap for **1 second**;
 - when you press the nozzle you will hear a small hiss: the foam applicator will be soaked in liquid freezing agent indicating the device is ready to freeze your wart or verruca.
 - If pressure is applied for too long, liquid may be deposited in the bottom of the cap. This is normal and it will quickly evaporate.
 - Leave the cap in place until all the liquid has evaporated or tip it away.
 - **Do not touch any excess liquid or the foam applicator because it will be extremely cold.**
- e). Hold the activator cap on the firm surface with one hand and remove the cap with the other hand. **Take care not to overturn the cap**
- f). Immediately after charging, holding the can in your hand, gently position the tip of the foam applicator on the centre of the wart or verruca.

IMPORTANT: exert gentle but constant pressure making sure that the sponge remains in contact with the wart or verruca for the entire treatment time, as detailed in the table above.

It will feel very cold, and a painful, aching or stinging sensation will occur as the wart or verruca freezes. It is important that you keep the foam applicator in contact with the wart or verruca for the specified contact time (i.e., avoid dabbing), unless you experience severe pain, in which case stop the treatment.



- g). After use, leave the assembly for 3 minutes (for the applicator to warm up). Then remove the foam applicator from the spout using a tissue and discard. It is important to avoid touching the foam applicator with your bare hands, even when it is no longer cold, because it may be contaminated with the wart virus which is highly contagious.
- h). To store the product safely without risk of the freezing contents being accidentally discharged, ensure there is no freezing liquid in the dome-shaped safety cap and replace it on the can, **but on this occasion make sure that the vertical arrow on the cap marked 'OFF' lines up with the triangle pointer marked on the plastic shoulder of the can**, then push the cap gently 'home'.

IMPORTANT: The can contains enough liquid for 12 treatments. Nevertheless, some may remain in the can after this. Empty the can by activating the nozzle and dispose of this liquid before throwing the can away.

4. WHAT TO EXPECT AFTER YOU FREEZE THE WART OR VERRUCA

After treatment, the skin in the treated area becomes white and then reddish. The freezing action will cause a temporary slight burning and painful sensation, which will gradually subside. The treated area will remain sensitive and a slight itchiness will be experienced. This is normal. In the few days following the freezing treatment a small blister may form. Protect using a waterproof dressing if necessary. In most cases, after 10-14 days the wart will fall off making way for the re-growth of healthy skin.

5. HOW TO LOOK AFTER THE TREATED AREA AFTER FREEZING

- Keep the area clean.
- Do not pick, scratch, pierce or cut the wart. Allow it to come away on its own.
- Do not puncture any blister that forms – protect it with a plaster if necessary.
- Shower, bathe or swim if you want to.
- Should an infection or other complication arise, consult a doctor.

6. SIDE EFFECTS

- When using freezing treatments temporary skin depigmentation may occur. The skin will gradually return to normal.
- As with all freezing methods of wart and verruca removal, treatment will be associated with the pain and/or discomfort and changes in skin appearance listed in Section 4 above.
- If used incorrectly, without following these instructions carefully, excessive freezing can cause permanent injury such as skin scarring or even damage to underlying nerves.
- As excessive freezing may cause damage to the tissue around the wart, do not hold the applicator in contact with common warts for longer than 20 seconds as shown in the table in section 3. For verrucas (excluding the toes and arch of the foot) do not hold the applicator in contact with the skin for more than 40 seconds.
- **Stop using** this product and tell your doctor, nurse or pharmacist if:
 - you experience unacceptable pain and/or discomfort or if irritation persists,
 - an infection or other complication arises. or;
 - any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

In the event of a serious accident (definition No. 65 article 2 of the Regulations 2017/745) in relation to this device, please notify Sixtem Life or report via Devices Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.

7. WARNINGS

- Pressurised container: heating may cause explosion.
- Keep away from heat, hot surfaces, sparks, open flames or other ignition sources.
- No smoking.
- Protect from sunlight.
- Do not expose to temperatures exceeding 50°C/122°F.
- Do not pierce or burn, even after use.
- Keep out of reach of children.
- Check the can is empty before discarding.
- For external use only.
- The product's expiry date is indicated on the bottom of the can.

8. FURTHER INFORMATION ABOUT BAZUKA SUB-ZERO

What freezing agent Bazuka Sub-Zero contains:

The freezing agent is a liquified mixture of Dimethyl ether and Liquid Propane Gas.

The pack contents:

The pack contains a pressurised aerosol can containing 50 ml of freezing agent, a dome-shaped safety cap, 12 foam applicators, and this instruction leaflet.

Sixtem Life Srl, Via Emilio Boni, 19 – 59100 Prato (PO) Italy. UK Responsible Person: Diomed Developments Limited, Hitchin, Herts, SG4 7QR, UK. Bazuka Sub Zero Registered Trademark held by Diomed Developments Limited.

This leaflet was last revised in October 2022.

Find out more about warts, verrucas and Bazuka products at: www.bazuka.co.uk
For LOT and expiry date see base of can.



Consult Warnings



Consult Instructions for Use



Medical Device

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