

bazuka

SUB-ZERO™

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

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** based on the cryotherapy method used by doctors.
 - Warts and verrucas are small excessive growths of skin caused by a type of virus. 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 or underneath the toes. They can be painful and often look like a small white ring of skin with a black dot 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 from one person to another.
- 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 for warts or verrucas located at sites that are difficult to reach, the assistance of a helper may be advisable.
- Bazuka Sub-Zero works by:
 - **quickly freezing the wart or verruca to its core**, causing the formation of a blister underneath the wart or verruca which helps it to loosen and fall off, often within a couple of weeks or so of freezing, revealing new, healthy skin underneath.
- 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 are pregnant or breast feeding;
- if you have diabetes or suffer from poor blood circulation to your hands or feet;
- anywhere on or near your face, armpits, breasts, bottom or genital (sex) area;
- on birthmarks, moles, warts with hairs growing from them, or any other spots;
- on areas where your skin is sensitive, damaged, cut, grazed, diseased or itchy; or
- at the same time as any other wart or verruca treatment.

Take special care when using this product:

- It is very important that you assemble it properly and 'charge' the special foam applicator following the detailed instructions in Section 3.

- It is very important that you use this product **cautiously**, applying it **with steady, gentle pressure only to the wart or verruca, and only for very short periods** (see the table in Section 3), otherwise it will cause too much freezing that will be unnecessarily painful, and may lead to permanent injury such as scarring and / or underlying nerve or tendon damage.
- If you are unsure whether you have a wart or verruca, or whether it is located at a site that is suitable for treatment with Bazuka Sub-Zero, ask your doctor, nurse or pharmacist before using this product.
- If you have lots of warts or verrucas that are close together, do not freeze them all at once (see Section 3).
- If you need to freeze a wart or verruca more than once, allow an interval of 2 weeks, and do not freeze the same one more than 3 times in total.
- Use each foam applicator only once. Never re-use them because this could spread the wart virus which is contagious.
- Once 'charged' with freezing agent, do not allow the foam applicator to come into contact with anything except the wart or verruca you intend to freeze.
- **Avoid spillage, and do not try to discharge the freezing contents of the aerosol can without using the dome-shaped safety cap**, as this may cause injury, and damage your possessions.
- The freezing agent is volatile and **extremely flammable**. Use the product only in well ventilated areas and well away from flames or ignition sources (eg burning cigarettes or anything else that might ignite it). Do not inhale vapour.

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

- Use it only to freeze individual warts and verrucas on sites for which it is recommended.
- Before freezing, to make the wart or verruca more susceptible to treatment, soak it in warm water for a few minutes then, after drying, gently file it with an emery board or pumice stone.
- 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 three 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 overleaf 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 | Use same contact time as shown for warts, determined according to verruca size. However, where appropriate, only for callused and/or deep-seated verrucas on heel and ball of foot (see diagram opposite), contact time can be increased up to a maximum of twice the corresponding time shown - i.e. depending on size, up to a maximum of between 20 and 40 seconds.  Area max. 20 sec. Area max. 40 sec. |
| Medium sized: from 2.5 mm to 5 mm ●● | 15 seconds | |
| Large: larger than 5 mm ●●● | 20 seconds | |

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.

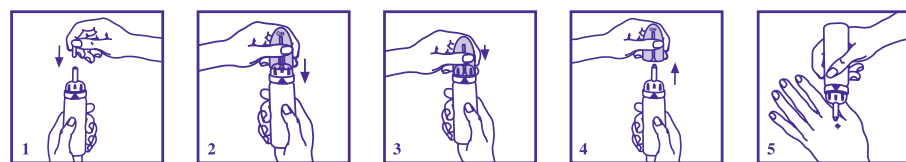
Assemble it as follows:

1. 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:

2. With the can standing upright, and the base resting on a suitable surface;
 - **gently** slide the dome-shaped safety cap over the spout and foam applicator, rotating it until the vertical arrow marked 'ON' lines up with the triangle shaped pointer marked on the plastic shoulder of the can.
3. 'Charge' the foam applicator by pressing down firmly on the dome-shaped safety cap for **3 seconds**;
 - you will hear a hissing sound, and;
 - viewed through the top of the dome-shaped safety cap, you will see the foam applicator become 'charged' with the liquid freezing agent, indicating that the device is ready to freeze your wart or verruca.
4. Carefully remove the dome-shaped safety cap, to expose the foam applicator, **but do not touch the foam because it will be extremely cold.**
5. Immediately after charging, pick up the assembly by the can and, keeping the foam applicator pointing straight down, freeze the wart or verruca by applying the foam applicator to the wart or verruca, taking care to apply it:
 - **only with constant light pressure;**
 - **only to the wart or verruca;** and
 - **only for a very short contact time** (see 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.



6. 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.
7. To store the product safely without risk of the freezing contents being accidentally discharged, replace the dome-shaped safety cap, **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'.

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

- Initially the treated area will turn white as it freezes, and a painful, aching or stinging sensation will occur.
- When the frozen area thaws, it may turn red, and the discomfort should fade quite quickly, disappearing completely after a few hours.
- A blister, that you may not be able to see, should form under the wart or verruca within a few days.
- Keep an eye on the treated area over the next two weeks;
 - if the wart or verruca gradually falls off, the treatment is complete, however;
 - if after 2 weeks you can still see or feel the wart or verruca, it may be necessary to freeze it again (up to twice more), leaving 2 weeks between each treatment.
- Ask for advice from your doctor, nurse or pharmacist if the wart or verruca does not go away after 3 freezes.

5. HOW TO LOOK AFTER THE TREATED AREA AFTER FREEZING

- Keep the area clean
- Do not pick or scratch it
- Do not puncture any blister that forms – protect it with a plaster if necessary
- Shower, bathe or swim if you want to

6. SIDE EFFECTS

- 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 and tendons.**
- If you spill the freezing agent on your clothes, fabrics, jewellery or metal and polished surfaces it may damage them permanently.
- **Stop using** this product and **tell** your doctor, nurse or pharmacist if:
 - you experience unacceptable pain and / or discomfort or if irritation persists, or;
 - any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

7. HOW TO STORE BAZUKA SUB-ZERO

- Keep in a cool, safe place out of the reach and sight of children.
- **Extremely flammable.**
- Do not expose to direct sunlight or temperatures higher than 50°C.
- Do not pierce or burn, even when empty.
- Do not store near anything that could set light to it.
- Do not use after the expiry date shown on the base of the aerosol can and carton. The expiry date refers to the last day of that month.
- After use, always replace the dome-shaped safety cap in the OFF position (or remove the safety cap from the aerosol can).
- Make sure the can is empty before disposal.

8. FURTHER INFORMATION ABOUT BAZUKA SUB-ZERO

What freezing agent Bazuka Sub-Zero contains:

The freezing agent is a liquified mixture of dimethyl ether, propane and isobutane.

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.

Manufactured by: Sixtem Life, 50019, Sesto Fiorentino, Italy, for Bazuka Sub-Zero registered trademark holder, Diomed Developments Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

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