



Instructions for Use – English Language (EN)

Products Covered by this IFU

Product Code	Mainit Silver Nitrate Caustic Pencil	Colour	Silver Nitrate Content	Potassium Nitrate Content
226504	Mainit Zilvernitraat Caustic Pencil 40% w/w, 1 box containing 1 Caustic Pencil Applicator	Red base & cap	40% w/w	60% w/w
226511	Mainit Zilvernitraat Caustic Pencil 95% w/w, 1 box containing 1 Caustic Pencil Applicator	Blue base & cap	95% w/w	5% w/w

Product Code	Mainit Silver Nitrate Caustic Applicator	Colour	Silver Nitrate Content	Potassium Nitrate Content
226506	Mainit Zilvernitraat Caustic Applicator 95% w/w, 1 Tube containing 100 Caustic Applicators in a bag	Blue stick	95% w/w	5% w/w
226505	Mainit Zilvernitraat Caustic Applicator 75% w/w, 1 Tube containing 100 Caustic Applicators in a bag	Yellow stick	75% w/w	25% w/w
2265061	Mainit Zilvernitraat Caustic Applicator 95% w/w, 1 Carton containing 10 bags, each with 10 Caustic Applicators	Blue stick	95% w/w	5% w/w
2265051	Mainit Zilvernitraat Caustic Applicator 75% w/w, 1 Carton containing 10 bags, each with 10 Caustic Applicators	Yellow stick	75% w/w	25% w/w

Notes to User

- The instructions tell you about using the product safely, please read them before use.
- Keep these instructions as you may need to read them again.

Device Description

The Mainit Zilvernitraatstift (Mainit Silver Nitrate Caustic Pencil and Caustic Applicator) is a Class IIa medical device intended for use by patients for the treatment of warts and verrucas by means of a caustic effect and healthcare professionals for the treatment of warts, verrucas, the residual umbilical cord, hyper granulation, aphthous stomatitis, haemostasis of superficial bleeding and nosebleeds by means of a caustic effect. The hardened silver nitrate tip is moistened with water, this dissolves the dried nitrate salts, which then chemically cauterises or burns the tissue. The subsequent caustic effect denatures cells and subsequently stimulates cell renewal, causing the skin to peel and healthy skin is formed.

The Mainit Zilvernitraatstift devices are for topical application and cover a range of strengths (40% w/w, 75% w/w and 95% w/w) and these vary in the respective concentrations of silver nitrate and potassium nitrate. The ingredients are present in a solidified mixture in the respective presentations. All are intended for topical application.

Please note, as indicated above, the 95% strength is presented in two forms – a Caustic Pencil and a Caustic Applicator. The 75% strength is presented as a Caustic Applicator only and the 40% strength as a Caustic Pencil only.

Intended Use

The Mainit Zilvernitraatstift (Mainit Silver Nitrate Caustic Pencil and Caustic Applicator) is a Class IIa medical device intended for use by patients for the treatment of warts and verrucas by means of a caustic effect. Intended for use by healthcare professionals for the treatment of warts, verrucas, the residual umbilical cord, hyper granulation, aphthous stomatitis, haemostasis of superficial bleeding and nosebleeds by means of a caustic effect. The device is intended for Short Term use to be used for local topical application to the skin (intact and damaged), mucus membrane of the mouth (but not past the pharynx) and nasal cavity. The Silver Nitrate Caustic Pencil is single patient use and intended for multiple applications. The Silver Nitrate Caustic Applicator is single use.

The Mainit Zilvernitraatstift (Mainit Silver Nitrate Caustic Pencil and Caustic Applicator) is not intended for use near eyes, on genital warts or sensitive areas of the body.

Use on children and vulnerable people should be only by an adult, a carer or Healthcare Professional.



Contraindications

- Do not use near your eyes.
- Do not use on genital warts.
- Do not use on sensitive areas of your body.
- Do not swallow.
- Do not use if you are allergic to Silver Nitrate or Potassium Nitrate.
- Do not use saline (or water known to contain salt or chlorides) to wet the tip of the Caustic Pencil or Caustic Applicator.

Warnings & Precautions

- Healthcare Professionals should use the lowest concentration possible for the condition being treated
- Lay Users should consult a Healthcare Professional or Pharmacist for advice on which concentration of Mainit Silver Nitrate Caustic Pencil or Caustic Applicator to use.
- Do not touch the tip of the Mainit Silver Nitrate Caustic Pencil or Caustic Applicator with your hands. Slight and temporary burning sensation on exposure to unintended broken skin.
- Protect your clothing and other objects while using the Mainit Silver Nitrate Caustic Pencil or Caustic Applicator. Silver Nitrate causes brown-black stains that cannot be removed with common cleaning or laundry detergents.
- Healthy skin that inadvertently comes into contact with the tip of the Mainit Silver Nitrate Caustic Pencil or Caustic Applicator should be carefully cleaned with running water and a sponge. Nevertheless, a harmless dark discoloration of these skin areas may occur. The dark discoloration will fade after about 10-14 days.
- If the Mainit Silver Nitrate Caustic Pencil or Caustic Applicator has come into contact with the eye immediately rinse under running water with the eyelid open for at least 5 minutes and then consult a doctor.
- When used around the mouth, be careful not to swallow any parts of the tip. If swallowing occurs, seek immediate medical attention (see section on when to contact a Healthcare Professional)
- If you forget to use the Mainit Caustic Pencil, do not apply double.
- Use caution when applying the wet Caustic Pencil or Caustic Applicator tip. If Silver Nitrate gets on unintentional areas of the hands, wash off immediately with soap and water, as this could result in accidental transfer to more sensitive areas of the body.
- The Caustic Applicator is single use only, do not reuse.
- The Caustic Pencil is single patient use, intended for multiple applications to the same area. Do not use on more than one patient as this presents a risk of infection.
- If you experience sensitivity to Silver Nitrate, stop using and consult a Healthcare Professional or Pharmacist.
- Use caution when drying the Caustic Pencil tip in between uses. If the tip is not dried properly, the tip may continue to dissolve, weakening the tip. Always examine the tip before and after use for signs of damage. If the tip is damaged, dispose of the Caustic Pencil.
- If you experience any pain after the use of the Mainit Silver Nitrate Caustic Pencils or Caustic Applicators, this can be controlled by administering an over-the-counter pain relief. If the pain worsens or is not controlled by over-the-counter pain relief, consult a Healthcare Professional or Pharmacist.

Performance and Clinical Claims

The performance and clinical claims for the Mainit Zilvernitraatstift Caustic Pencils and Caustic Applicators are as follows:

- The application of silver nitrate provides immediate arrest of epistaxis during initial treatment
- Patients with aphthous ulcers report reduced oral pain after single treatment
- Over 70% of patients report satisfaction with outcomes following use of silver nitrate to treat verruca pedis
- Silver nitrate may heal granuloma in a single application

Instructions for Use

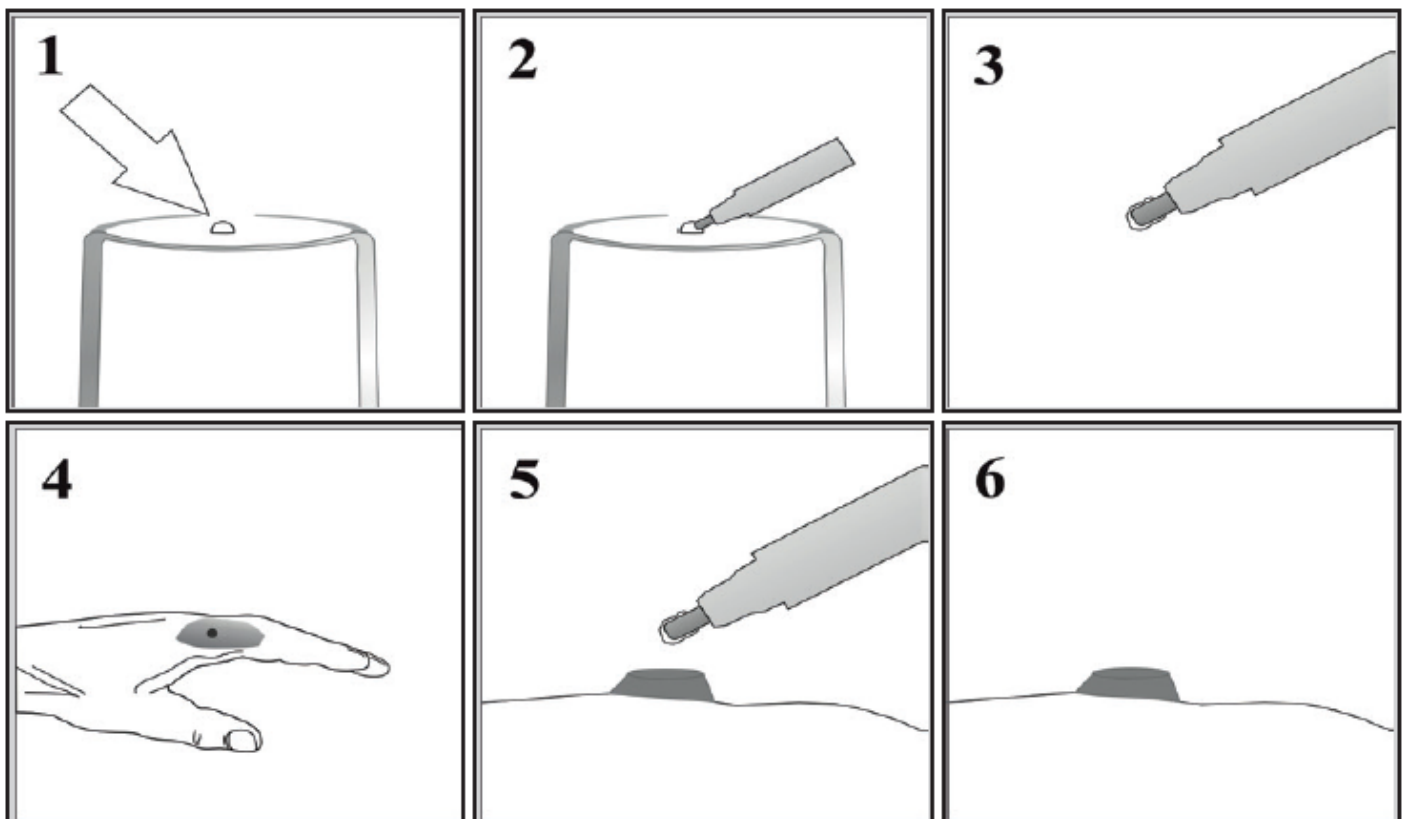
The recommended application schedule is:

- Apply once every 2 to 3 days until the desired result is achieved.
- Multiple applications may be required.
- Do not use for more than 14 days. If there is no improvement, please consult a doctor or pharmacist.

Before application of Silver Nitrate:

- Source a small amount of clean water such as tap water (do not use saline, see contraindications section)
- Source a clean non-absorbent surface such as an upturned drinking glass or steel cup.
- Source a paper tissue.
- Source petroleum jelly: Apply petroleum jelly to the healthy skin around the area where Silver Nitrate will be applied.
- Prepare a clean, stable area to work from which is free from distraction and which is protected from potential staining e.g. Lay protective sheets.
- Examine the tip of the Caustic Pencil or Caustic Applicator. If there are signs of tip fracture or damage, dispose of the device and source another Caustic Pencil or Caustic Applicator.

How to apply the Mainit Silver Nitrate Caustic Pencil or Caustic Applicator:



Step 1:

- Put a single drop of clean water on a non-absorbent surface (such as an upturned drinking glass).

Step 2:

- Place the tip of the Caustic Pencil or Caustic Applicator into the water drop. Gently move the tip in the water drop for approximately 20 seconds.

Step 3:

- The tip of the Caustic Pencil or Caustic Applicator is now coated with the water drop. The water drop coated tip contains dissolved Silver Nitrate ready to transfer to the application area.

Step 4:

- Do not allow the water or tip to come into contact with healthy skin, clothing, furniture or other surfaces as this may stain a brown-black colour.
- Healthy skin can be protected using a barrier cream such as petroleum jelly.

Step 5:

- Use the tip of the Caustic Pencil or Caustic Applicator, (which is coated with the water drop containing dissolved Silver Nitrate), to transfer the water to the application area.
- Make sure the whole application area is coated with water from the Caustic Pencil or Caustic Applicator tip.
- Do not rub the Caustic Pencil or Caustic Applicator tip on the area.
- Do not apply pressure on the Caustic Pencil or Caustic Applicator tip.
- Note: If the Caustic Pencil or Caustic Applicator tip fractures or breaks, ensure all pieces are recovered, disposed of in paper tissue and dispose of the Caustic Pencil or Caustic Applicator.

Step 6:

- Allow the application area to dry before contact with any other surface.
- The application area will stain black after a short period of time, and this is expected.

After application of Silver Nitrate:

- Caustic Pencil:
 - Using a paper tissue, dry the tip of the Caustic Pencil, and the remains of the water drop on the upturned drinking glass and dispose of the paper tissue.
 - Examine the Caustic Pencil tip, if the tip appears dry and intact, replace the Caustic Pencil Cap and store in original packaging, in a cool dry place away from direct sunlight.
 - If the tip appears fractured or damaged, dispose of the Caustic Pencil.
- Caustic Applicator:
 - Dispose of the single use Caustic Applicator.
 - Using a paper tissue, dry the remains of the water drop from the upturned drinking glass and dispose of the paper tissue.

Storage & Handling

- Keep out of reach of children.
- Do not use after the expiry date (see date following Use-By-Date symbol on device and packaging)
- Store in original packaging to protect from light and moisture.
- Store in a cool, dry place and away from direct sunlight.
- Store between 5°C and 25°C and up to 60% Relative Humidity

Substances contained in the Medical Device

- The active substance is Silver Nitrate
- Other substances are Potassium Nitrate

When to Contact a Healthcare Professional

Ask a doctor or pharmacist for advice before using Mainit Silver Nitrate Caustic Pencil or Caustic Applicator if you:

- experience sensitivity to using Silver Nitrate
- have recently used or are using any medication.
- pregnant or breast feeding, think you may be pregnant or are planning to have a baby.
- have used the device for 14 days with no signs of improvement.
- have any unusually discoloured or unusually shaped skin changes that are not unambiguously identifiable as 'wild flesh' or as common warts or verruca, the Mainit Silver Nitrate Caustic Pencils or Caustic Applicators should only be used under the supervision of a physician.
- have exposed the eye to Silver Nitrate

If you swallow the tip of a Mainit Silver Nitrate Caustic Pencil or Caustic Applicator, go to the hospital casualty department straight away and seek medical attention. Take the packaging and this instruction leaflet with you to inform the doctor what

you have used. If you have swallowed, you may have pain in the mouth, produce more saliva, diarrhoea, feeling sick, being sick (vomit may be stained black, loss of consciousness or fits).

Reporting a Serious Incident

If use of the device results in a serious incident, as defined in Medical Device Regulation (EU) 2017/745, please contact either Mainit B.V or the Competent Authority in your country of use (see [https://ec.europa.eu/growth/sectors/medical-devices/contacts; Vigilance contact points menu](https://ec.europa.eu/growth/sectors/medical-devices/contacts;Vigilance%20contact%20points%20menu)).

CE mark and use of harmonized symbols

Symbol	Explanation
	Medical Device
	Catalogue number
	Batch code
	Unique device identifier
	Use-by date
	Caution
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Caustic Applicators: Do not re-use
	Consult instructions for use.
	Medical Device Manufacturer
	CE Mark (including SGS Belgium NV Notified Body number)
	Do not use if package is damaged or opened
	Country of manufacture. CC shall be replaced by country code GB to indicate Great Britian
	Caustic Pencils: Single Patient multiple use
	Store between 5°C and 25°C
	Store up to 60% Relative Humidity



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