NEW ZEALAND DATA SHEET

1. SAFE T PEN (Phenol 89% v/v solution)

SafeTPen, Phenol 89% v/v solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol 89% v/v with blue colouring (FD&C Blue No.1 Powder).

3. PHARMACEUTICAL FORM

Blue coloured solution in a glass ampule contained within a sealed tube with an applicator.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Enable the application of 89% liquified phenol to the nail bed (matrix) following the removal of a toenail (nail matrixectomy) to prevent nail re-growth, through chemical cauterisation.

4.2 Dose and method of administration

Intended to be used and administered by suitably qualified medical professionals such as, Podiatrists, General Practitioners, Plastic and Orthopaedic surgeons.

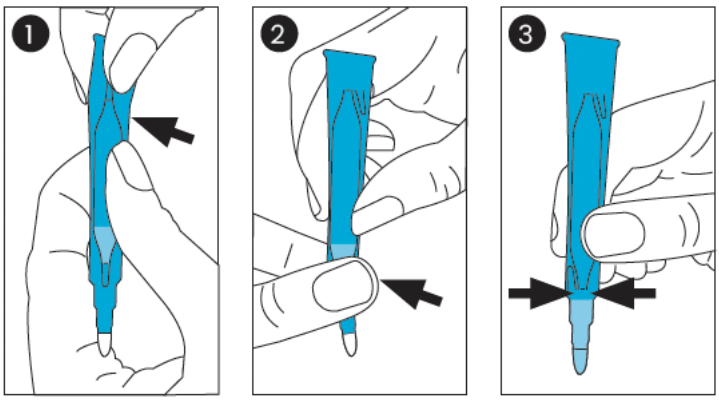
Apply required amount to nail bed (matrix). Each ampule contains 0.4 mL solution.

<u>Instructions for Use</u>

Do NOT attempt to break glass ampule, other than at marked ends.
Do NOT attempt to break in the middle or remove glass from plastic outer tube.
Do NOT attempt to remove the applicator tip in any way.
Do NOT use the product unless the liquid exhibits a blue colour.

Apply appropriate PPE gear: Medical gown, medical gloves, goggles and/or visor before activation & use.

1. Snap – using both hands to hold the SafeTPen, gently snap the top ampule tip
2. Snap – repeat the same process with the bottom ampule tip
3. Squeeze – holding the SafeTPen like a pen, use your fingertips, to lightly squeeze the device to load the absorbent applicator tip. Only use the required amount of phenol.



NOT to be used on infants or children under the age of 6.

4.3 Contraindications

- Hypersensitivity or Allergies to phenol or FD&C Blue No.1 Powder.
- There are many contraindications to digital surgery that should be assessed that are not specifically related to phenol use.
- Diminished vascular supply or peripheral vascular disease.
- Overt bacterial infection of the operative site is a relative contraindication to chemical cauterisation.
- Use caution with people who have a bleeding disorder or who are taking anticoagulant therapy.
- Diabetic patients susceptible to infection, foot ulcers, circulatory issues.
- Pregnancy of medical professional or patient. Best practice is to postpone nail surgery until after pregnancy and breastfeeding period.
- Not to be used on infants or children under the age of 6.

4.4 Special warnings and precautions for use

- Phenol is a chemical classified as 'Hazardous' and should be handled with care. Appropriate PPE gear should always be worn.
- Do NOT attempt to break glass ampoule anywhere other than at the marked break points
- Do NOT attempt to break glass in the middle of the ampoule or remove the ampoule from the plastic outer tube.
- Do NOT attempt to remove applicator tip at any time for any reason.
- Do NOT use if there are signs the integrity of the ampoule or sleeve tube has been compromised prior to opening.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Phenol has been shown to have fetotoxic effects and be absorbed across the placental barrier. Use in pregnancy for the medical professional and patient is not recommended. Best practice is to postpone nail surgery until after pregnancy and breastfeeding period.

No evidence to suggest an effect on fertility given the medicine is only intended to have a localised effect on the nail bed.

4.7 Effects on ability to drive and use machines

The phenol active has no influence on the ability to drive and use machines. However this medicine is intended to be used as part of nail matrixectomy which may affect the patients ability to drive and use machine due to local anaesthetic use.

Clinician guidance is recommended.

4.8 Undesirable effects

Pain is the most common complication following nail surgery and is more likely to occur when infection is present before the procedure. Even with meticulous patient preparation and technique, postoperative infection may occur.

Skin irritation and skin burns may occur if skin sensitivities are present, or product is not used according to manufacturer instructions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose

Overdose is unlikely with this medicine.
This medicine is intended only to be used and administered by suitably qualified medical professionals such as Podiatrists, General Practitioners, Plastic and Orthopaedic surgeons.

Only the required amount of phenol should be used.

Each applicator is intended to administer a single dose and is not for reuse.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

Global Medical Device Nomenclature (GMDN) Code: 63682, Nail matrixectomy solution.
A non-sterile solution of phenol intended to be applied to the nail bed (matrix) following the removal of an in-grown toenail to prevent nail re-growth (nail matrixectomy) through chemical cauterization. The solution may be contained within a specialized applicator (e.g., vial with swab). It is intended for professional use. After application, this device cannot be reused.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

FD&C Blue No.1 Powder

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 30 °C in a well-ventilated secure (locked) area.

6.5 Nature and contents of container

A heat-sealed plastic tube consisting of; a further sealed glass vial containing 0.4 mL of a non-sterile solution of 89% liquid phenol, and blue colouring (0.002g), with an integrated applicator tip. The devices are packed individually in a clear Polythene pouch and are made available in boxed units of 12.
After application, this device cannot be reused.

6.6 Special precautions for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.
Do not use the product if the packaging has been damaged or if there are signs that the solution has leaked from the vial on opening.
Appropriate PPE must be worn at all times when disposing and or handling.
Avoid all unnecessary contact with skin by wearing protective clothing as serious burns may result.
Avoid contact with eyes by wearing appropriate eye protection.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Whiteley Medical Limited
4 Loft Place
Kumeu 0810
AUCKLAND
Phone: 09 929 2747

9. DATE OF FIRST APPROVAL

7 August 2025

10. DATE OF REVISION OF THE TEXT

7 August 2025