

TECHNICAL DATA SHEET

(REF 64812 – 600017 – 600022 – 600023 - 600024)



LATEX FREE



1 COMPOSITION

VERSOL® Sodium Chloride 0.9 %

- Sodium Chloride.....0.9 g
- Water for Injections.....to 100 ml

VERSOL® Sterile Water

- Water for Injections.....to 100 ml

The raw materials (Water for Injections - obtained by osmosis and distillation - and Sodium Chloride) comply with relevant European Pharmacopoeia Monographs.

Sterile (moist heat sterilisation) and pyrogen free solutions.

2 APPROVED USE

VERSOL® Sterile Water is used for wound irrigation in pre-, peri-, and postoperative stages.

VERSOL® Sodium Chloride 0.9% is used for wound cleansing, wound irrigation or dressings in pre-, peri-, and postoperative stages.

Not for injection.

These solutions of isotonic sodium chloride and water are intended to be used by healthcare professionals in hospital, community medical and care facilities. Versol® Sodium Chloride 0.9% can be used by patients at home during the post-treatment period, when prescribed.

3 PRESENTATIONS AND VOLUMES

VERSOL® bottles are made of Polypropylene (PP).

Polypropylene is transparent, so the solution inside the bottle can be checked by visual inspection.

Polypropylene as a sealed container is water-tight, light, unbreakable at room temperature, inert and does not react with the solution.

The liner inside the cap in contact with the solution (plug) is also made of Polypropylene. At the base of the cap is a Viskering seal which guarantees bottle tamper resistance.

For product differentiation, the shell, that part of the cap not in contact with the solution, is coloured as follows:

- Blue for Water
- Green for Sodium Chloride 0.9%

The bottle is made in a square shape to make it easier to store and grasp. The bottles are available in two volumes: 500 ml and 1000 ml.

4 PRECAUTIONS FOR USE

- **Not for injection.**
- Do not use unless solution is clear, the container is undamaged, and the seal intact.
- Sterile single-use device.
- The contents of an opened bottle should be used promptly to minimise the risk of microbial growth.
- Discard any unused solution.
- There is a risk of contamination if solution is re-used.
- After use, discard the container and any unused solution according to local waste disposal practice.

5 SHELF LIFE – STORAGE AND USE CONDITIONS

- The shelf-life is two years.
- Store below 30°C.
- The product can be heated up to 40°C immediately prior to use.
- Do not store in a cold area. Do not freeze.

6 CODES

Aguettant Code	Medical Devices	GTIN code	Pack Size
600023	VERSOL® SODIUM CHLORIDE 0.9% 500 ml	3700567700210	20
600024	VERSOL® SODIUM CHLORIDE 0.9% 1000 ml	3700567700241	10
600017	VERSOL® STERILE WATER 500 ml	3700567700159	20
600022	VERSOL® STERILE WATER 1000 ml	3700567700180	10

Medical devices class IIa (directive 93/42/EEC).
Laboratoire AGUETTANT Certification : NF EN ISO 13485.