

Product Specifications

Brand : Klinion®
Product : Prefilled Syringe with 0.9% Sodium-Chloride

Product description

Klinion® Prefilled Syringes 0.9% Sodium-Chloride (NaCL) are ready to use polypropylene syringes for single use. Klinion® Prefilled Syringes 0.9% NaCL have a Luer (male) connector at the distal end of the barrel and are prefilled with an isotonic 0.9% NaCL solution and sealed with a tip cap.

Klinion® Prefilled Syringes 0.9% NaCL are available with a sterile fluid path or sterile unit, which are sterilized via moist heat or radiation respectively.

Intended use

Klinion® Prefilled Syringes 0.9% NaCL are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. For flushing only.

Klinion® Prefilled Syringes 0.9% NaCl **XS** are externally sterile and can be used on a sterile field.

Klinion® Prefilled Syringes 0.9% NaCl **SP** are sterile fluid path only and cannot be used on a sterile field.

Classification

Class IIa under the Medical Devices Regulations (SI 2002 No. 618, as amended) and
Class IIa under Regulation (EU) 2017/745 Medical Device Regulation (MDR).

Packaging & Product Reference

Product Reference	Description	Size (*)	Peel Pouch (pcs)	Inner Carton (pcs)	Outer Carton (pcs)
C0880364	KLINION 3ML PREFILLED SALINE SYRINGE SP	3 ml	1	30	480 (16 x 30)
C0880365	KLINION 5ML PREFILLED SALINE SYRINGE SP	5 ml	1	30	480 (16 x 30)
C0880366	KLINION 10ML PREFILLED SALINE SYRINGE SP	10 ml	1	30	480 (16 x 30)
C0880367	KLINION 3ML PREFILLED SALINE SYRINGE XS	3 ml	1	30	240 (8 x 30)
C0880368	KLINION 5ML PREFILLED SALINE SYRINGE XS	5 ml	1	30	240 (8 x 30)
C0880369	KLINION 10ML PREFILLED SALINE SYRINGE XS	10 ml	1	30	240 (8 x 30)

Product Specifications

Product Reference	Description	Size (*)	EAN Peel Pouch	EAN Inner Carton	EAN Outer Carton
C0880364	KLINION 3ML PREFILLED SALINE SYRINGE SP	3 ml	06971564462907	16971564462904	26971564462901
C0880365	KLINION 5ML PREFILLED SALINE SYRINGE SP	5 ml	06971564462914	16971564462911	26971564462918
C0880366	KLINION 10ML PREFILLED SALINE SYRINGE SP	10 ml	06971564462921	16971564462928	26971564462925
C0880367	KLINION 3ML PREFILLED SALINE SYRINGE XS	3 ml	06971564462938	16971564462935	26971564462932
C0880368	KLINION 5ML PREFILLED SALINE SYRINGE XS	5 ml	06971564462945	16971564462942	26971564462949
C0880369	KLINION 10ML PREFILLED SALINE SYRINGE XS	10 ml	06971564462952	16971564462959	26971564462956

*Sizes are approximate

Features

- Single use
- Sterile

Contra-Indications

Klinion Prefilled Syringes 0.9% NaCl are not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated. Do not use in cases where the administration of sodium or chloride could be clinically detrimental (e.g. Hyponatremia, fluid retention).

Directions for use

Check instructions for use of drug manufacturer to ensure compatibility with 0.9% NaCl solution prior to use. If 0,9% NaCl solution is not compatible, follow the drug manufacturer instructions for flushing practices, or first flush the vascular access device (VAD) with a compatible solution to remove traces of the medication followed by flushing with 0.9% NaCl solution as a locking solution.

1. Visually inspect the package. Do not use if the wrapping is damaged or the solution is leaking.
2. Remove the wrapping.
3. Inspect if the solution is clear, the tip cap is in place, the syringe is intact and there is no evidence of leakage.

Do not use if the solution is cloudy or contains particulate matter or if the syringe is damaged or not intact.

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4. Depress the plunger with the tip cap on to release the stopper seal.
5. Unscrew the syringe cap from the syringe ensuring not to touch the syringe luer connector to avoid contamination.
6. Hold the syringe upright and push the plunger until the air is expelled from the syringe.
7. Attach with luer connector on injection site and prime to flush with proper force.
8. Discard the empty syringe properly according to local policy. Do not reuse syringes

Precautions

- Do not use if the packaging is damaged or not intact.
- Do not use if the product has expired.
- Do not use if the syringe or stopper is damaged in any way that suggests or indicates leakage.
- Do not use if solution is discoloured, contains a precipitate or has any type of suspended matter.
- Do not reuse, for single use only. Re-use may lead to infection or other illnesses.
- Discard any partially used product.
- Sterile if pouch and seal are intact.
- For use under the guidance of a healthcare professional.
- Some patients may experience a transitory discomfort during flushing. This minor effect ceases shortly after the procedure is completed. In case a serious incident has occurred in relation to the device, inform Medeco BV as listed on the packaging, your local distributor and your local healthcare authority.

Presence of specific components

Component	Present
Latex	No
Phthalates	No
Substances of animal origin	No
Substances of human origin	No
Blood or blood derivates	No
BPA	No
Heavy metals	No

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Sterilization

Klinion® Prefilled Syringes 0.9% NaCl **XS** are Gamma sterilized.

Klinion® Prefilled Syringes 0.9% NaCl **SP** are Steam sterilized.

Storage conditions

The products should be stored at controlled temperature 15-25°C, in a cool well-ventilated and dry place away from direct sunlight.

Shelf life

Klinion® Prefilled Syringes 0.9% NaCL have a shelf-life of 5 years from production date, when stored under specified conditions.

Picture



Product. ref.: C0880364 and C0880367

Approval	Name	Date	Signature
Associate Category Management Director	Susanne van den Berg		
RA Specialist	Alexandra Maria da Silva Duarte		