Praxiject™ 0.9% NaCl

Prefilled Syringe with 0.9% Sodium Chloride Injection USP

Sterile – Non Pyrogenic – Single Use – Rx Only

Does not contain preservatives. Not made with natural rubber latex.

INDICATIONS FOR USE

Only for flushing vascular access devices. May be placed on a sterile field.

CONTRAINDICATIONS

Not for dry product reconstitution or for medication dilution. Not for direct intravenous injection.

WARNINGS AND PRECAUTIONS

Use aseptic technique. Single use only. Do not reuse. Do not use if package is opened or damaged. Do not use if the cap/adapter on the syringe is not intact. Visually inspect the contents of each prefilled syringe for clarity, particulate matter, precipitate, discoloration and leakage prior to use. Do not use if any of the aforementioned is observed. Do not allow air to be trapped in the fluid path. Do not resterilize. Sterile unless package opened or damaged.

ADVERSE REACTIONS

No known adverse reactions when the product is used as indicated.

INSTRUCTIONS FOR USE

Use aseptic technique.

1. Aseptically open package containing the 0.9% Sodium Chloride solution prefilled syringe. Visually inspect product for particulate matter and discoloration prior to use. Heed all WARNINGS AND PRECAUTIONS.
2. Remove protector as required. Expel air from syringe. Do not allow air to be trapped in fluid path. Use only with compatible luer lock connectors.
3. In accordance with the institution's protocol, flush the lumen of the vascular access device (VAD) with 0.9% Sodium Chloride solution to remove any blood, medication or other substance remaining in the VAD.
4. Remove and discard unused portions and empty syringes according to the institution's biohazardous waste policy.

ACTION

0.9% Sodium Chloride Injection USP solution is a sterile, aqueous solution having approximately the same osmotic pressure and composition as extracellular fluids. It is non-irritating to tissues. It is used to flush vascular access devices in order to maintain catheter patency and to prevent contact between incompatible medications or fluids.

PRODUCT DESCRIPTION AND PACKAGING

Praxiject™ 0.9% NaCl is a single use plastic syringe, prefilled in various fill volumes and packaged in a plastic heat-sealed pouch. Each prefilled syringe contains 0.9% Sodium Chloride Injection USP solution with no preservatives. Praxiject™ 0.9% NaCl is available in different syringe formats and fill volumes.

STORAGE AND STABILITY

Store Praxiject™ 0.9% NaCl prefilled syringes at 15°C to 30°C (59°F to 86°F), protected from direct sunlight and freezing. Do not use after the Use-by date on product labels.

SYMBOLS ON PRODUCT LABELS

Glossary of Symbols				
Symbol	**Title**	**Meaning**	**Standard**	**Reference**
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2016	5.1.1
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2016	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2016	5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1:2016	5.2.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2016	5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1:2016	5.4.2
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1:2016	5.4.4
Rx only	Prescription device	Caution: Federal law restricts this device to sale by or on the order of a physician	21 CFR 801.109	-

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MedXL Inc. 285 Av Labrosse, Pointe-Claire, QC H9R 1A3, Canada

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