

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

UPDATED: Sodium chloride 0.9% 100 mL intravenous solution – 8 June 2023

What's new in this update?	Details of S19A alternative included
Details of affected product(s)	Baxter® sodium chloride 0.9% 100 mL (AHB1307) – ARTG 48515 Freeflex® sodium chloride 0.9% 100 mL (FAH3015) – ARTG 144609
Reason for communication	Disruption to supply due to manufacturing issues and increased demand.
Date issue made apparent	March 2023
Estimated resolution date	Unclear

Main indications and use

Sodium chloride 0.9% intravenous solution is used to correct deficiencies in hydration and electrolyte imbalance. It may also be used as a diluent for compatible intravenous medicines.

Situation

There is a current disruption to the supply of sodium chloride (Baxter® and Freeflex®) 0.9% 100 mL solutions due to manufacturing issues and increased demand. The estimated date of return of supply is unclear at this stage.

Alternative agents

- Facilities should continue to order their regular brand of sodium chloride 0.9% 100 mL intravenous solutions (B Braun®, Baxter® or Fresenius Kabi®) from their regular wholesaler/supplier unless advised otherwise from HealthShare NSW.
- Facilities are encouraged to reserve existing sodium chloride 0.9% 100 mL intravenous solutions for fluid restricted patients.
- Sodium chloride 0.9% 50 mL and 250 mL products from B Braun®, Baxter® and Fresenius Kabi® can also be used (where clinically appropriate). Consider appropriate fluid balance management where alternative volumes are used.
- Alternative diluents (for example glucose 5% and compound Sodium Lactate Infusion [Hartmann's]) can be considered in place of sodium chloride 0.9% intravenous solution where clinically appropriate and compatible.
- Facilities unable to obtain sufficient supply of 100 mL products, alternative volumes or diluents to meet usual demand, should contact HealthShare NSW.

International alternatives

An alternative product from the 0.9% Sodium chloride injection (Baxter USA) in Vialflex bag 100 mL has been approved for supply in Australia until 30 April 2024 under Section 19A of the Therapeutic Goods Act. It is currently available for purchase from Baxter Healthcare. The product is identical in active ingredient and strength to the Australian Product, but differs with regard to pH, storage requirements and the type of port protector utilised. For further information regarding the differences between the US alternative and the Australian registered product, please refer to the [factsheet](#) from Baxter Healthcare.

ARTG products

Supplier	50 mL container	100 mL container	250 mL container
B Braun®	Sodium chloride 0.9% intravenous infusion ARTG 154967	Sodium chloride 0.9% intravenous infusion ARTG 98311	Sodium chloride 0.9% intravenous infusion ARTG 98312
Baxter®	Sodium chloride 0.9% injection bag (AHB1306/AHB1363) ARTG 19477	Sodium chloride 0.9% injection bag (AHB1307/AHB1364) ARTG 48515	Sodium chloride 0.9% injection bag (AHB1322) ARTG 48517
Fresenius Kabi®	Sodium chloride 0.9% (Freeflex®) injection bag ARTG 144596	Sodium chloride 0.9% (Freeflex®) injection bag ARTG 144609	Sodium chloride 0.9% (Freeflex®) injection bag ARTG 144632

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Precautions, safety issues and other considerations associated with alternatives

- Utilising an alternative volume of a sodium chloride solution, when diluting a medication for intravenous use will affect the final concentration of the solution. Refer to the [Australian Injectable Drugs Handbook](#) to ensure the concentration within the acceptable range for administration.
- Some medicines (e.g. ciclosporin, tacrolimus and diazepam) are incompatible with PVC. Refer to [Australian Injectable Drugs Handbook](#) for further information.
- The following features of alternative sodium chloride solutions should be considered:

	Presentation	Storage	Max volume that can be added 50 mL container	Max volume that can be added 100 mL container	Max volume that can be added 250 mL container
B Braun® (50 mL, 100 mL & 250 mL)	Ecoflac Plus® container*	Below 25°C	70 mL	40 mL	90 mL
Baxter® (50 mL, 100 mL & 250 mL)	Viaflex® plastic (PVC) container	Below 30°C (Below 25°C for S19A)	140 mL	90 mL	60 mL
Fresenius Kabi® (50 mL, 100 mL & 250 mL)	Freeflex® composite plastic laminate bags	Below 25°C	70 mL	50 mL	75 mL

*The B Braun Ecoflac Plus® container has been designed in such a manner that it does not require a giving set with an air-vent. The container empties automatically under atmospheric pressure, except for a small residual portion of fluid at the end of infusion, thus preventing the inadvertent entry of air into the system. Training may be required for clinicians on the appropriate use of this presentation.

Impacts of this communication on clinical practice

Actions to address the disruption to the supply of sodium chloride 0.9% 100mL intravenous solution should be planned and implemented at a local level by the Drug and Therapeutics committees in consultation with relevant clinicians. Alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy issues

[PD2022 032 Medication Handling](#)

Key contacts

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