



SAFETY NOTICE 019/24

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Issue date:	11 July 2024		
Content reviewed by:	Medication Safety Expert Advisory Committee (MSEAC)		
	Medication Shortage Assessment and Management team (MSAM)		
	ACI Emergency Care Institute		
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit		
KEY MESSAGE:	NSW Health facilities are aware of the ongoing disruption to supply of adrenaline (epinephrine) (Aguettant®) 1:10,000 (1 mg/10 mL) pre-filled syringe.		
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance		
REQUIRED ACTION:	 Distribute Safety Notice to all relevant clinicians and clinical departments where adrenaline (Aguettant) 1:10,000 (1 mg/10 mL) pre-filled syringes are held, prescribed, and/or administered, and include this Safety Notice in relevant handovers and safety huddles. Undertake a local risk assessment and incorporate the below recommendations to manage the disruption of supply of adrenaline (Aguettant) 1:10,000 (1 mg/10 mL) pre-filled syringe. Ensure a system is in place to document actions taken in response to this Safety Notice. Report any incidents associated with this disruption to supply into the local incident management system e.g. ims+. Confirm receipt and distribution of this Safety Notice within 72 hours to: CEC-MedicationSafety@health.nsw.gov.au. 		
DEADLINE:	COB 16 July 2024		
We recommend you also inform:	Directors, Managers and Staff of: Emergency and Intensive Care Departments NSW Ambulance Services Pharmacy Nursing/Midwifery Medical Services (e.g., cardiology) Drug and Therapeutics Committees Digital Health/ICT Clinical Product Managers Infection Prevention and Control Other relevant clinicals, departments and committees.		
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx		
	http://internal.health.nsw.gov.au/quality/sabs/index.html		
Review date:	February 2025		

Contact: Clinical Excellence Commission

02 9269 5500

CEC-MedicationSafety@health.nsw.gov.au



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Situation

There is a current disruption to the supply of adrenaline (epinephrine) (Aguettant®) 1:10,000 (1 mg/10 mL) prefilled syringe (ARTG 282377) due to manufacturing issues until at least 15 August 2024. Refer to the Therapeutic Goods Administration (TGA) Medicine shortage reports database for the most up-to-date information about supply impact dates.

Supply of an alternative Australian registered product adrenaline (LINK®) 1:10,000 (1 mg/10 mL) injection BP pre-filled syringe (ARTG 210672) remains available, however, the product is presented as a glass pre-filled syringe which is **not** compatible with all connector valves.

Supply of adrenaline (Aspen®) 1:10,000 (1 mg/10 mL) solution for injection ampoule (ARTG 162463) remains available.

Background

Adrenaline is a non-selective adrenergic agonist used in the treatment of cardiac arrest, heart failure, cardiogenic shock, septic shock and anaphylactic reactions.

Adrenaline 1:10,000 (1 mg/10 mL) pre-filled syringes and ampoules are listed on the <u>NSW Medicine Formulary</u> without restriction. Adrenaline is included in multiple Emergency Care Assessment and Treatment (<u>ECAT</u>) protocols.

Adrenaline pre-filled syringes may be administered through a connector valve, which are used to connect peripheral and central vascular access devices to intravenous lines. In 2022, Safety Notices were issued surrounding the incompatibility of intravenous connector valves with glass pre-filled syringes (these have since been archived). Refer to **Table 1** for a list of compatible connector valves.

Assessment

Alternative adrenaline products remain available, including:

- Adrenaline (LINK) 1:10,000 (1 mg/10 mL) injection BP pre-filled syringes
- Adrenaline (Aspen) 1:10,000 (1 mg/10 mL) solution for injection ampoules

Adrenaline (LINK) 1:10,000 (1 mg/10 mL) injection BP pre-filled syringes

The alternative product available from LINK is presented in a glass pre-filled syringe that requires use of a compatible connector valve (and adaptor where required, for example with the ICU Medical MicroClave connector valve). A list of compatible connectors can be found in **Table 1**. Where compatible connectors are not available in clinical areas, there is a risk of delayed administration of adrenaline to patients.

Adrenaline (Aspen) 1:10,000 (1 mg/10 mL) solution for injection ampoules

The use of adrenaline (Aspen) 1:10,000 solution for injection ampoules in place of pre-filled syringes may pose risk of injury due to their presentation in a glass ampoule and requirements for drawing up doses in a timely manner for emergency/resuscitation situations.

While the pre-filled syringes are presented as a single dose and individually packaged to assist with protection from light, the adrenaline (Aspen) 1:10,000 solution for injection ampoules are presented in a pack of 10 ampoules. If utilising smaller quantities for resuscitation trays or emergency trolleys, clinicians should consider the need to protect individual ampoules from light.

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Recommendations

- A review of stock holdings of adrenaline 1:10,000 products should be conducted across each facility/health service considering unique areas of storage including emergency trolleys, emergency backpacks, and resuscitation trays/kits.
- Ensure clinicians are:
 - Notified of the disruption to supply of the adrenaline (Aguettant) 1:10,000 pre-filled syringe.
 - o Informed of the alternative adrenaline 1:10,000 products available and the recommendations outlined below.
- Where LINK pre-filled syringes are utilised:
 - Ensure that a compatible connector valve (outlined in **Table 1**) is available and stored with the pre-filled syringe. Contact your local Clinical Product Manager to determine which compatible valves are available.
 - o Ensure staff are familiar and trained on the use of the compatible connector valves.
 - o In the unlikely event of blockage or inability to administer adrenaline from a LINK pre-filled syringe, despite use of a compatible connector valve, consider:
 - Changing to a new connector valve even if it is another of the same kind.
 - Use of adrenaline ampoules to administer the dose.
- Where the adrenaline 1:10,000 (Aspen) injection ampoules are used, ensure the product is administered
 in accordance with NSW Health Medication Handling Policy Directive (PD2022_032) and that the
 product is protected from light prior to administration.
- Ensure a copy of this Safety Notice is stored within all emergency trolleys until the disruption to supply has resolved.
- Where caresets, 'PowerPlans' or equivalent in electronic Medication Management (eMM) systems are
 in use, consider the need to update configurations (for example, order sentences and product
 catalogues) where required to reflect change in products based on local availability.



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Table 1: Compatible valve connectors for adrenaline (LINK) 1:10,000 pre-filled syringes*

Supplier	ARTG product code	Product	
Baxter HealthCare	345081	Clearlink needle free luer activated devices	
B Braun	136030	Ultrasite Valve	
	246695	MaxPlus Needleless Connectors	
Becton Dickinson	96767	Q-Syte Connector	
	246696	SmartSite Needle Free Valve	
	235965	H-Port Valve Connector	
ICU Medical		 N-Pulse Valve Connector 	
ICO Medicat	235966	T-Site Valve Connector	
	135689	D1000 Tego Connector	
CONNECTORS TO BE USED WITH 011-CS25 Adaptor (ARTG 269617)			
	207069	Microclave Connector	
ICU Medical		Microclave Clear Connector	
		 Neutron 	

^{*}As per information provided by LINK Healthcare at time of publication other connectors that are not listed in **Table 1** are **not recommended** to be used.