

# Disruption to supply of adrenaline (epinephrine) 1:10,000 (1 mg/10 mL) pre-filled syringes and safety considerations



## **N** SAFETY NOTICE 030/24

Issue date:	1 November 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 disruptions to supply of adrenaline pre-filled syringe products and associated safety considerations including details of an urgent TGA product defect alert associated with adrenaline (epinephrine) (Link®) 1:10,000 (1 mg/10 mL) pre-filled syringe (ARTG 210672).
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"> <li>1. Distribute this Safety Notice to all relevant clinicians and clinical departments where adrenaline 1:10,000 (1 mg/10 mL) products are held, prescribed, and/or administered, and include this Safety Notice in relevant handovers and safety huddles.</li> <li>2. Undertake a local risk assessment and incorporate the below recommendations to manage this disruption of supply and safety considerations related to the use of the Link product.</li> <li>3. Ensure a system is in place to document actions taken in response to this Safety Notice.</li> <li>4. Report any incidents associated with this disruption to supply and/or product defects as outlined in the <i>Recommendations</i> section.</li> <li>5. Confirm receipt and distribution of this Safety Notice within 72 hours to: <a href="mailto:CEC-MedicationSafety@health.nsw.gov.au">CEC-MedicationSafety@health.nsw.gov.au</a>.</li> </ol>
DEADLINE:	COB 6 November 2024
We recommend you also inform:	Directors, Managers and Staff of: <ul style="list-style-type: none"> <li>• Emergency and Intensive Care Departments</li> <li>• Operating Theatres and Perioperative Services</li> <li>• NSW Ambulance Services</li> <li>• Pharmacy</li> <li>• Nursing/Midwifery</li> <li>• Medical Services (e.g., cardiology)</li> <li>• Drug and Therapeutics Committees</li> <li>• Digital Health/ICT</li> </ul> Clinical Product Managers Other relevant clinicals, departments and committees.
Website:	<a href="https://www.health.nsw.gov.au/sabs/Pages/default.aspx">https://www.health.nsw.gov.au/sabs/Pages/default.aspx</a> <a href="http://internal.health.nsw.gov.au/quality/sabs/index.html">http://internal.health.nsw.gov.au/quality/sabs/index.html</a>
Review date:	February 2025

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## What is updated in this Safety Notice from SN:019/24?

- This Safety Notice replaces Safety Notice 019/24 *Disruption to supply – Adrenaline (epinephrine) (Aguettant®) 1:10,000 (1 mg/10 mL) pre-filled syringe* which has now been **rescinded**.
- The disruption to supply now affects both the Aguettant® and Link® adrenaline 1:10,000 (1 mg/10 mL) prefilled syringe products.
- An urgent TGA product defect alert has been issued regarding adrenaline (epinephrine) (Link®) 1:10,000 (1 mg/10 mL) pre-filled syringe (ARTG 210672) – [RC-2024-RN-00914-1](#). Information from this alert surrounding blocked syringe bores has been included within this Notice.

## Situation

There is an ongoing disruption to the supply of Australian registered adrenaline (epinephrine) 1:10,000 (1 mg/10 mL) pre-filled syringe products due to manufacturing issues and unexpected increases in demand. The products subject to this disruption to supply are:

- adrenaline (epinephrine) (Aguettant®) 1:10,000 (1 mg/10 mL) pre-filled syringe (ARTG 282377)
- adrenaline (epinephrine) (Link®) 1:10,000 (1 mg/10 mL) pre-filled syringe (ARTG 210672).

Refer to the Therapeutic Goods Administration (TGA) [Medicine shortage reports database](#) for the most up-to-date information about supply impact dates.

At the time of publication, 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 [NSW Medicine Formulary](#) without restriction. Adrenaline is included in multiple Emergency Care Assessment and Treatment (ECAT) 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

Facilities may need to switch between brands of pre-filled syringes, or utilise the ampoules, during the disruption to supply based on availability. Important safety considerations are outlined below:

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

- This product 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.

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- There have also been reports of Link pre-filled syringes with blocked bores which have made it difficult or impossible to administer this product in an emergency (despite use of a compatible connector). The manufacturer is investigating the cause of these blocked syringes.
- An urgent TGA product defect alert has been disseminated regarding both of these issues ([RC-2024-RN-00914-1](#)).

## 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.

## 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 disruptions to supply of adrenaline 1:10,000 pre-filled syringe products.
  - Informed of the adrenaline 1:10,000 products available for use within your facility and the recommendations outlined below.
- Where Link pre-filled syringes are utilised:
  - Clinicians should be aware of the serious defects related to this product including blocked bores and connector compatibility issues. Ensure a back-up syringe is immediately available in case of a defect.
  - Ensure that a compatible connector valve (outlined in **Table 1**) is available and stored with the pre-filled syringe. Local Clinical Product Managers are asked to communicate which compatible valves are available locally and include images of the products in their communication where possible.
  - Ensure staff are familiar and trained on the use of the compatible connector valves.
  - In the event of 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 an alternative pre-filled syringe.
    - 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 during storage in line with manufacturer recommendations.

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- Ensure a copy of this Safety Notice is displayed and visible within clinical and patient care areas storing adrenaline pre-filled syringes.
- 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.
- Ensure any instances of product defects, are:
  - reported to the TGA at: <http://www.tga.gov.au/reporting-problems>
  - notified in the local incident management system (ims<sup>+</sup>)
  - reported to the drug sponsor.
- Any concerns regarding the disruption to supply should be escalated to [CEC-MedicationSafety@health.nsw.gov.au](mailto:CEC-MedicationSafety@health.nsw.gov.au).

**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
Becton Dickinson	246695	• MaxPlus Needleless Connectors
	96767	• Q-Syte Connector
	246696	• SmartSite Needle Free Valve
ICU Medical	235965	• H-Port Valve Connector • N-Pulse Valve Connector
	235966	• T-Site Valve Connector
	135689	• D1000 Tego Connector
<b>CONNECTORS TO BE USED WITH 011-CS25 Adaptor (ARTG 269617)</b>		
ICU Medical	207069	• Microclave Connector • 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.