



Australian Government
Department of Health, Disability and Ageing

URGENT PRODUCT ALERT*

LEVEL: Retail

CLASS: Class II

REFERENCE: RC-2025-RN-00621-1

DATE AGREED: 24/07/2025

PRODUCT: **BICILLIN L-A benzathine benzylpenicillin tetrahydrate
1,200,000 Units / 2.3 mL suspension for injection pre-filled
syringe with needle**

Lot Numbers: LT0106, HJ3234

Product code: F000156028

Expiry Dates: 30 Sep 2027, 30 Sep 2026

ARTG: 147169 - BICILLIN L-A benzathine benzylpenicillin tetrahydrate
1 200 000 Units / 2.3 mL suspension for injection pre-filled
syringe with needle

SPONSOR: Pfizer Australia Pty Ltd

**SPONSOR CONTACT
INFORMATION:** 1800 629 921 – Pfizer Customer Service

REASON: Particulates have been identified during visual inspection of
certain lots of BICILLIN L-A 1,200,000 Units/ 2.3 mL.

In the event that impacted product is administered to a patient,
there is a potential for patient discomfort, a mild hypersensitive
reaction, rash, oedema, infections, or blocked needle diameter
resulting in inability to deliver a full dose.

There have been no product quality complaints or adverse
events to date for the impacted batches related to this problem.

**PROPOSED CUSTOMER
ACTIONS:** Replacement stock is currently unavailable due to a current
shortage of the medicine.

If customers have any affected stock, Pfizer suggests the
following to mitigate the risk:

1. Perform careful visual inspection of any syringe prior to administration to confirm that it contains no particulate matter.
2. Discard the syringe should particulate matter be observed. Do not administer to patients.
3. If abnormal resistance is encountered from the syringe plunger during administration to a patient, discontinue usage. Discard the used syringe and assess if a replacement dose is required.
4. Follow usual procedures to monitor patients post-administration for reactions including, but not limited to, local foreign body reactions and infections, and report any and all suspected adverse events to the TGA via <http://www.tga.gov.au/reporting-problems> and to Pfizer on: 1800 675 229 or by email to: AUS.AEReporting@pfizer.com.

For any medical information customers can call 1800 675 229 – Pfizer Medical Information.

The sponsor is expected to dispatch letters to all affected customers within two business days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods subject to this market action and have not received a notification letter.**

Product Distribution: 52 wholesalers and hospitals nationally excluding ACT

Product export status: New Zealand

This information has been published in the TGA's searchable database, <https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00621-1>

*For further details about Market Actions, please refer to - <https://www.tga.gov.au/safety/market-actions>