

Government of Western Australia Department of Health Communicable Disease Control Directorate

POTENTIAL TEMPORARY SHORTAGE OF BICILLIN LA™

Dear Clinicians,

I am writing to provide an update on the expected shortage of Bicillin LA.

You may have already seen the attached letter from Pfizer Australia that was sent to pharmacies and pharmacy wholesalers about a potential temporary shortage of Bicillin LA[™]. Temporary shortages may recur throughout 2024.

The Communicable Disease Control Directorate (CDCD) is working with the Chief Pharmacist to stocktake Bicillin LA[™] supplies in Western Australia and determine if prioritisation strategies will be required.

Pfizer Australia has informed the Department of Health that they are working closely with the Therapeutic Good Administration (TGA), the National Aboriginal Community Controlled Health Organisation and Rheumatic Heart Disease Australia, in addition to Chief Pharmacists in jurisdictional health departments to prevent stockpiling and ensure equitable supply of Bicillin LA[™].

Pfizer Australia has also advised that the *Doc Bag Express*, a medical supplier that supplies Pharmaceutical Benefits Scheme (PBS) Doctor's bag medications, has enough stock of Bicillin LA[™] until December 2023.

An alternative brand of benzathine benzylpenicillin, approved by the TGA under section 19a, and PBS listed from 1 January 2024 is available via ORSPEC Pharma if Bicillin LA[™] stocks are depleted.

The reconstituted volume and dosing schedule (as stated in the product information) of the alternative product may not be suitable for administering to all children, depending on their weight.

The Australian Commission on Safety and Quality in Health Care (ACSQHC) is developing a national guidance document on how to use the alternative product, including clinical and practical information, which will be openly accessible via the TGA website in the coming weeks.

A potential advantage of the alternative product is that it can be reconstituted with lignocaine.

CDCD recommends that clinicians:

- 1. Continue to use benzathine benzylpenicillin for the treatment of syphilis, acute rheumatic fever and rheumatic heart disease prophylaxis and other diseases for which benzathine benzylpenicillin is first line treatment.
- 2. Do a stocktake of current Bicillin LA[™] supplies and order appropriate amounts to treat your patient cohort for 1-2 months (please avoid stockpiling).
- 3. Consider suitable alternatives to treatment with benzathine benzylpenicillin, where appropriate on a case-by-case basis and with specialist advice.
- 4. Order the alternative product from ORSPEC Pharma (+61 24 339 4239 or <u>customerservice@orspecpharma.com</u>) as required.
- 5. Contact your <u>local public health unit</u> if you are having difficulty sourcing benzathine benzylpenicillin to treat a patient with syphilis

CDCD will continue to monitor the situation and provide regular updates as further information becomes available. If you have any queries, please email Dr Donna Mak at <u>donna.mak@health.wa.gov.au</u>.

Dr Clare Huppatz

A/DIRECTOR, COMMUNICABLE DISEASE CONTROL DIRECTORATE

Infectious Diseases Health Alerts: <u>https://ww2.health.wa.gov.au/Articles/F_I/Health-alerts-infectious-diseases</u> Subscribe to Infectious Diseases Health Alerts via the <u>CDCD subscription page</u>

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Pfizer Australia Pty Ltd ABN: 50 008 422 348 Level 15-18, 151 Clarence Street Sydney, NSW, 2000

2nd November 2023

Dear Healthcare Professional,

AN UPDATE ON THE NOW LIKELY TEMPORARY SUPPLY INTERRUPTION FOR: BICILLIN L-A benzathine benzylpenicillin tetrahydrate 1,200,000 units/2.3 mL suspension for injection syringe with needle [ARTG 147169]

Please be advised of an update to a now **likely** supply interruption of the following presentation listed below.

Presentation	Pack Size	Pfizer Item Code	Estimated Wholesaler Out of Stock Date	Back in Stock Date
Bicillin L-A benzathine benzylpenicillin tetrahydrate 1,200,000 units/2.3 mL suspension for injection [ARTG 147169]	10 vials	PF_F000156028	Mid-Late November 2023	Mid-January 2024

Pfizer Australia would like to provide further updates following the 16th October correspondence. We have currently constrained our stock at our warehouse to be able to more readily manage the stream of supply to market. We have been exploring ways to allocate stock equitably, but with varying levels of stock sitting at individual sites and with only inaccurate estimates of those details, to ensure nobody goes without, the **precautionary decision** has been made to proceed with an S19A arrangement through ORSPEC Pharma. **For more information about the S19A option, ORSPEC Pharma can be contacted on: Ph: 61 24 339 4239 or e-mail:** <u>customerservice@orspecpharma.com</u>. This product will come as a **vial of powder for suspension for injection + a glass ampoule with solvent for suspension for injection. Please contact ORSPEC Pharma for additional details about the S19 product.**

The reason for this temporary interruption in supply does not impact the quality, safety or efficacy of the finished product already on the market. The next supply to be recovered at the manufacturing site is expected in December 2023 and expected to be available in early January 2024.

We understand and regret the challenges that this situation poses to patients. Pfizer fully realises the importance of this medicine to patients. We thank you for your understanding and apologise for any inconvenience caused to you and your patients. Pfizer is working diligently to minimise patient impact and resolve the disruption in supply. Pfizer will provide updates as appropriate.

Complete information regarding the approved indications for Bicillin L-A (benzathine benzylpenicillin tetrahydrate 1,200,000 units/2.3 mL suspension for injection) can be found in the Product Information available at https://www.tga.gov.au/.

Please direct all medical enquiries regarding for Bicillin L-A to Pfizer Medical Information on 1800 675 229 from 9am-5pm AEDT, Mon-Fri or via <u>www.pfizermedicalinformation.com.au</u> for assistance.

Should you have any enquiry on stock availability, please contact Pfizer Trade Operations on 1800 629 921.

Adverse Event Reporting

Reporting of suspected adverse events is important for the monitoring of the safety of all medicines. Any adverse events which are experienced with these products should be reported by healthcare professionals and/or patients to the TGA via <u>http://www.tga.gov.au/reporting-problems</u> or to Pfizer on 1800 675 229 or by email to AUS.AEReporting@pfizer.com

Yours sincerely,

Ymbai

Yuen Lai Hospital & Community Medicine Medical Lead Pfizer Australia and New Zealand