Bicillin L-A (benzathine benzylpenicillin) shortage: information for clinicians, pharmacies and health services

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OFFICIAL

This fact sheet provides interim information on the national shortage of Pfizer Bicillin L-A, recommendations on antibiotic prioritisation, and advice on accessing the alternative benzathine benzylpenicillin product.

Key messages

- There is an ongoing national shortage of Pfizer Bicillin L-A (benzathine benzylpenicillin tetrahydrate) prefilled syringes (600,000 units per syringe and 1.2 million units per syringe) that is expected to continue into 2024.
- Shortage of the Bicillin L-A 1.2 million unit syringe is expected to continue for several months into 2024 while the 600,000 unit syringe will likely remain in limited supply until November 2024.
- The shortage may impact the management of conditions such as syphilis, acute rheumatic fever / rheumatic heart disease and other group A streptococcal diseases.
- The Therapeutic Goods Administration has approved an alternative benzathine benzylpenicillin product (benzathine benzylpenicillin 1.2 million unit vial) from Brancaster Pharma under a Section 19A arrangement of the *Therapeutic Goods Acts 1989*. This product requires reconstitution and has different administration instructions to the Bicillin L-A syringe.
- Since 1 January 2024, the alternative Brancaster Pharma benzathine benzylpenicillin product is subsidised by the Pharmaceutical Benefits Scheme. It can be ordered through Orspec Pharma.
- Clinicians, pharmacies and health services providing care to patients with conditions that typically
 require treatment or prevention with benzathine benzylpenicillin are recommended to conserve
 adequate stock for priority conditions and groups and consider the use of appropriate alternative
 antibiotic agents in suitable patients.
- The shortage situation continues to evolve and may change on short notice. Clinicians, pharmacies
 and health services are advised to anticipate and prepare for disruptions to benzathine
 benzylpenicillin supply during 2024.



Advice to support clinical practice during the shortage

Temporary prioritisation of antibiotic prescribing and medication stock management are recommended for clinicians and health services during the benzathine benzylpenicillin shortage.

- 1. Consider whether antibiotics are indicated for patient care.
- 2. Consider whether benzathine benzylpenicillin is indicated for a priority condition. If so, consider whether the Brancaster Pharma product be given instead of Pfizer Bicillin L-A.
- Consider whether an alternative antibiotic agent can be prescribed instead of benzathine benzylpenicillin, and seek advice from an infectious diseases specialist, <u>Therapeutic Guidelines</u> and/or relevant condition-specific clinical guidelines as required.

Prioritised use of benzathine benzylpenicillin

Benzathine benzylpenicillin should be prioritised for use in the following conditions during the shortage:

- treatment of definite, probable and possible acute rheumatic fever
- secondary prophylaxis of acute rheumatic fever and/or rheumatic heart disease
- treatment of syphilis in those with proven or suspected infection and their recent sexual contacts, particularly pregnant women and their partners or in people where the likelihood of non-adherence to alternative oral therapy is high.
- patients who require treatment for group A streptococcal infection of the respiratory tract and skin
 who are at high risk of acute rheumatic fever, rheumatic heart disease or post-streptococcal
 glomerulonephritis, where oral therapy is not acceptable or the likelihood of non-adherence is high.

If benzathine benzylpenicillin is required, consider prescribing the **Brancaster Pharma benzathine** benzylpenicillin product where possible.

Pfizer Bicillin L-A prefilled syringes should be conserved for use in:

- neonatal and paediatric patients.
- health care settings where the use of the alternative benzathine benzylpenicillin medication is not appropriate, including rural and remote settings and some Aboriginal Medical Services or Aboriginal Community Controlled Health Organisations.
- patients who are unable to receive the Brancaster Pharma product or alternative antibiotic agents, such as due to allergies or other contraindications.

Alternative antibiotic agents

During the benzathine benzylpenicillin shortage, clinicians should consider prescribing an **alternative antibiotic agent** where appropriate.

Refer to the Australian <u>Therapeutic Guidelines</u>, relevant condition-specific guidelines and/or infectious disease specialists for advice.

Alternative benzathine benzylpenicillin medication

Information on the Section 19A benzathine benzylpenicillin

The Therapeutic Goods Administration approved the importation and supply of the overseas-registered Brancaster Pharma benzathine benzylpenicillin product (benzathine benzylpenicillin 1.2 million unit vial) in Australia under Section 19A arrangements of the *Therapeutic Goods Act 1989*. From 1 January 2024, this medication is subsidised by the Pharmaceutical Benefits Scheme.

The Brancaster Pharma product can be used as an alternative medication to Pfizer Bicillin L-A prefilled syringes in the treatment and prevention of conditions such as syphilis, acute rheumatic fever / rheumatic heart disease and other group A streptococcal diseases. Both Pfizer Bicillin L-A and Brancaster Pharma product contain long acting benzathine benzylpenicillin. The recommended dose and frequency for these conditions are unchanged with the Brancaster Pharma product, which is considered safe for people of all ages and for use in pregnancy and breastfeeding.

It is important to note that there are differences in the presentation, storage, additional expedients and administration of Brancaster Pharma product compared to Pfizer Bicillin L-A. Notably, the Brancaster Pharma product must be reconstituted and results in a larger administration volume.

In Australia, the Brancaster Pharma product is being ordered and supplied by Orspec Pharma.

Procurement of the Section 19A benzathine benzylpenicillin in Victoria

Health services and pharmacies are recommended to stay up to date on the ongoing benzathine benzylpenicillin shortage situation, closely monitor their medication stock and plan for forecasted usage.

Services that anticipate an ongoing demand of benzathine benzylpenicillin are recommended to:

- continue contacting their regular distributors to try and procure Pfizer Bicillin L-A.
- order the Brancaster Pharma product (benzathine benzylpenicillin 1.2 million unit vial) as soon as possible to prevent disruptions in medication stock.
- implement interim prioritisation of antibiotic prescribing and medication stock management to conserve benzathine benzylpenicillin products, including Pfizer Bicillin L-A and the Brancaster Pharma product.
- consider liaising with other local health services and community pharmacies, particularly in regional and rural areas, to support patient pathways for accessing benzathine benzylpenicillin.

Pharmacies and health services should contact Orspec Pharma on 02 4339 4239 for details on ordering and supply of the Brancaster Pharma product (benzathine benzylpenicillin 1.2 million unit vial).

Where benzathine benzylpenicillin is the only suitable medication for a patient and there are difficulties with access to supply, clinicians and health services are recommended seek advice from their Local Public Health Unit: Local Public Health Units | health vic.gov.au.

Additional resources

For more information on the Bicillin L-A shortage, see:

- Therapeutic Goods Administration: About the shortage of Bicillin L-A (benzathine benzylpenicillin tetrahydrate) prefilled syringe for injection | Therapeutic Goods Administration (TGA)
- Therapeutic Goods Administration: <u>Medicine Shortages Information Initiative | Therapeutic Goods</u>
 Administration (TGA)

For more information on antibiotic prioritisation during the shortage and use of the Brancaster Pharma benzathine benzylpenicillin product, see:

- Australian Commission on Safety and Quality in Health Care Fact Sheet
- Rheumatic Heart Disease Australia: <u>Brancaster clinical guidance | Rheumatic Heart Disease Australia (rhdaustralia.org.au)</u>
- Australian Injectable Drugs Handbook: AIDH Login (hcn.com.au)

For more information on alternative antibiotic agents, refer to the Australian <u>Therapeutic Guidelines</u>, relevant condition-specific guidelines and/or infectious disease specialists for advice.

For details on ordering and supply of the Brancaster Pharma benzathine benzylpenicillin product, contact Orspec Pharma on 02 4339 4239.

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