

BENZATHINE BENZYL PENICILLIN

This Fact Sheet is intended as a guide only, to complement existing publications from different jurisdictions in response to the shortage of **Bicillin L-A® prefilled syringes**. The current replacement product is a S19A alternative from Brancaster Pharma Ltd; the leaflet will provide detailed administration advice. The recommendations in this leaflet are based on review of the literature and expert consensus.



There is currently an Australian-wide shortage of benzathine benzylpenicillin

Priority indications

During the shortage, stocks of benzathine benzylpenicillin should be prioritised for the following conditions:

- Acute rheumatic fever – definitive, probable, and possible infections
- Secondary prophylaxis of acute rheumatic fever and rheumatic heart disease
- Treating syphilis – proven and suspected infections (especially in pregnancy)
- Group A streptococcal infections in patients at high risk of acute rheumatic fever and rheumatic heart disease or post-streptococcal glomerulonephritis where oral therapy is unacceptable, or the likelihood of non-adherence is high
- Bicillin L-A® prefilled syringes: reserve for regional and remote settings and in young children unable to receive and tolerate larger volumes through the intramuscular route

The S19A alternative product – Brancaster Pharma Ltd

Do **NOT** refer to the product information inside the primary packaging or found online for dosing, as this differs with Australian Guidelines. The recommended benzathine benzylpenicillin dosing and frequency for acute rheumatic fever, rheumatic heart disease and syphilis remains **unchanged** (see useful resources)



Important notes on the S19A alternative product

- Each vial contains benzathine benzylpenicillin, 1.2 million units, powder for suspension and is manufactured by Brancaster Pharma Ltd (UK) and sourced by Orspec Pharma Ltd (AU) for use within Australia
- This product contains the same active ingredient as Bicillin L-A® prefilled syringes but **differs** in presentation, storage, preparation, and excipients
- The reconstituted product is **estimated to be 4.5 mL** – this is almost double the current volume for administration using the Bicillin L-A® prefilled syringe
- Both Bicillin L-A® prefilled syringes and the S19A alternative contain **soy lecithin** – there is conflicting information on how to manage use in patients with known peanut or soy allergies. The nature of the reaction should be considered and if available, the advice of an immunologist should be sought prior to administration

Using the S19A alternative product

- Store at **room temperature** – do not freeze or refrigerate
- Reconstitute the vial with 3.5 mL of water for injection (supplied) or lignocaine/lidocaine 1%
- After a uniform suspension is formed, the reconstituted solution must be used **immediately**
- All intramuscular injections should be administered in line with local procedures and guidelines

Dose	Administration
Doses ≥ 1.2 million units	
1.2 million units (approx 4.5 mL)	Adults: Administer as a single intramuscular injection. The ventrogluteal site is preferred.
2.4 million units (approx 9 mL) [#]	Adults: Administer as two intramuscular injections (at separate ventrogluteal sites). Up to 5 mL can be administered as a single IM injection.
Doses < 1.2 million units*	
450,000 units (approx 1.8 mL)	Adults: The ventrogluteal site is preferred Children: The vastus lateralis is preferred; up to 3 mL can be administered as a single intramuscular injection Neonates: The vastus lateralis is preferred; Administration volume to be calculated based on weight; up to 1 mL can be administered as a single intramuscular injection
600,000 units (approx 2.4 mL)	
[#] A dose of 2.4 million units is made up using 2 x 1.2 million units vials [*] If a part-dose is required, first check the TGA Information about major medicine shortages for current advice and refer to the Australian Injectables Handbook	

Useful resources

- The Australian Therapeutic Guidelines
- The Australian Injectables Handbook
- The Australian Medicines Handbook
- The RHD Australia – Guidelines for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease, 3rd Edition
- Australian Society of Infectious Diseases guidelines: Management of perinatal infections, 3rd Edition
- [TGA medicines shortage reports database](#)
- [Orspec Pharma](#) – statement on alternative supply arrangement of benzathine benzylpenicillin under S19A of the Therapeutic Goods Act 1989
- [Product information of S19A alternative](#) – Brancaster Pharma
- [Australian Commission on Safety and Quality in Health Care](#): Safety considerations during Bicillin L-A® supply disruption