Antibiotic Alert

National shortage of benzathine benzylpenicillin (Bicillin L-A®)

This alert provides information for healthcare staff regarding the shortage of benzathine benzylpenicillin (Bicillin L-A®) and provides guidance from the SA expert Advisory Group on Antimicrobial Resistance (SAAGAR) for addressing this shortage.

> Benzathine benzylpenicillin (Bicillin L-A®) is a long-acting penicillin antibiotic administered by intramuscular injection, and is used to treat syphilis, and for the treatment and prevention of acute rheumatic fever and rheumatic heart disease.

Summary of issues

> Both strengths of benzathine benzylpenicillin (Bicillin L-A®) (600,000 I.U. / 1.17 mL **AND** 1.2 million I.U. / 2.3 mL) are in short supply due to a manufacturing issue and increases in consumer demand. The shortage is expected to continue to November 2024 for the lower strength product, and until February 2024 for the higher strength product.

> An alternative brand, not currently registered in Australia, has been authorised for supply by the Therapeutic Goods Administration (TGA) under Section 19A (S19A) of the *Therapeutic Goods Act* until 30 March 2024.

Comparison of Bicillin L-A® and the S19A-approved brands

	Registered products	S19A-approved product
Brand	Bicillin L-A®	Brancaster Pharma, UK
Strength	Benzathine benzylpenicillin 600,000 I.U. / 1.17 mL **AND** Benzathine benzylpenicillin 1.2 million I.U. / 2.3 mL	Benzathine benzylpenicillin 1.2 million I.U. per vial
Dose form	Suspension for injection	Powder and solvent for suspension for injection
Pack presentation	10 x prefilled syringes	1 x vial of powder 1 x 5mL ampoule of water for injection
Storage conditions	Store at 2°C to 8°C. Refrigerate, do not freeze.	Store below 25°C
Excipient ingredients	- Sodium citrate - Water for injection - Soya lecithin - Carmellose sodium - Povidone - Methyl hydroxybenzoate - Propyl hydroxybenzoate	Powder - Soya lecithin - Polysorbate 80 - Carmellose sodium - Sodium citrate, anhydrous - Povidone Solvent - Water for injection
PBS-listed	Yes	To be PBS listed from January 2024

Key points for consideration

- Bicillin L-A® and the S19A-approved brand both contain soya lecithin. In patients with peanut or soy allergies contact an immunologist for advice.
- The S19A-approved product has a larger reconstituted volume than the Bicillin L-A® brand. The contents of the vial (of the S19A-approved product) should be reconstituted with at least 3.5 mL of diluent (The vial comes with a 5mL ampoule of water for injection).
- To reduce pain at the injection site, 1% lidocaine may be used to reconstitute the contents of the vial of the S19A-approved product. The minimum volume of diluent for reconstitution is 3.5mL; reconstitution of the vial can be done with just lidocaine 1% or a combination of water for injection and lidocaine 1%.
- When lidocaine solution is used as a diluent:
    - Contraindications to lidocaine must be excluded prior to administration
    - Patients should be monitored for systemic adverse effects (e.g., numbness of mouth and tongue, tinnitus, confusion, seizures, coma, tachycardia, hypertension, ventricular arrhythmias)
    - A reduced volume of lidocaine 1% (with the remainder of the total volume made up with water for injection) may be considered in paediatric patients given their smaller muscle size, to reduce the risk of systemic adverse effects.
- While the S19A-approved product may be ordered via community pharmacies, there may be a lead time of approximately 7 to 10 days.
- A higher strength benzathine benzylpenicillin 2.4 million I.U. / vial product is available internationally but is also not registered in Australia. The higher strength product does not have S19A approval by the TGA, however prescribers may access the product via the Special Access Scheme (SAS). The 2.4 million I.U. vial should be reconstituted with a minimum of 5mL of diluent. The final reconstituted volume of approximately 7mL should be divided and administered across two injection sites. The higher strength product will not be PBS listed.
- Pfizer are reserving a small quantity of restricted stock for the most at need patients who cannot tolerate the alternative product. To enquire for access for a particular patient, email Pfizer customer service at: customerservice.australia@pfizer.com or phone 1800 629 921.

References:

1. Therapeutic Goods Administration, Department of Health. Australian Government. https://www.tga.gov.au.
2. Australian Medicines Handbook Pty Ltd. https://amhonline.amh.net.au/ 2020 edition. Accessed 06 November 2023.
3. Brancaster Pharma Limited. (2021). Benzylpenicillin benzathine 1.2 million I. U. powder and solvent for suspension for injection: Product Information.
4. Brancaster Pharma Limited. Benzylpenicillin benzathine 2.4 million I.U. powder and solvent for suspension for injection. https://www.medicines.org.uk/emc/product/11044/smpc#about-medicine. Accessed 27 November 2023.

For more information

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