

Benzathine benzylpenicillin safety during supply disruption

This fact sheet aims to assist health service organisations (HSOs) and clinicians to understand and manage safety considerations related to the disrupted supply of benzathine benzylpenicillin (Bicillin L-A) in Australia.

Key messages

The Therapeutic Goods Administration (TGA) has notified of a [worldwide shortage of benzathine benzylpenicillin: Bicillin L-A prefilled syringes](#).

To limit supply disruption, the TGA has approved the importation and supply of alternatives under Section 19A (S19A) of the Therapeutic Goods Act.

The **S19A alternatives differ from the Australian registered Bicillin L-A** in presentation, preparation, storage, and excipients. There are **safety and suitability considerations** due to these differences (see **Table 1** for comparison).

Bicillin L-A pre-filled syringes should be **conserved** for patient cohorts, where the **S19A alternatives** may not be suitable, for example, in paediatric patients.

Seek advice from Infectious Diseases/Microbiology and/or the Therapeutic Guidelines: Antibiotic (including the [Antibiotic prescribing in primary care: summary table](#)) for alternative agents if Bicillin L-A pre-filled syringes are unavailable and the S19A alternatives are unsuitable.

This fact sheet is for use during a period of shortage only. If adequate stock of the Australian registered product of benzathine benzylpenicillin: Bicillin L-A (Pfizer brand) is assured, health services and clinicians should return to using it in line with relevant local and national evidence-based guidelines.

The same safety and suitability considerations should be applied for additional brands of benzathine benzylpenicillin available via the Special Access Scheme (SAS) but **not approved by the TGA under S19A**.

Background

This fact sheet has been developed by the Australian Commission on Safety and Quality in Health Care (the Commission) at the request of the Department of Health, Disability and Ageing.

Benzathine benzylpenicillin is a long-acting antibiotic formulation that is typically used in uncomplicated syphilis and rheumatic heart disease (RHD) prevention. Refer to the [Therapeutic Guidelines: Antibiotic](#) for additional information.

Situation

The TGA has advised of a [worldwide disruption](#) to the supply of:

- Benzathine benzylpenicillin tetrahydrate (Bicillin L-A) 600,000 units/1.17 mL suspension for injection pre-filled syringe
- Benzathine benzylpenicillin tetrahydrate (Bicillin L-A) 1,200,000 units/2.3 mL suspension for injection pre-filled syringe.

Updates and information about the shortage, and return to supply dates, are available on the TGA [Medicine Shortage Reports Database](#).

To alleviate the impact of this shortage, the TGA has approved the importation and supply of overseas-registered alternatives under Section 19A (S19A) of the Therapeutic Goods Act 1989. For full details of current approvals, including duration of approval, see the [Section 19A Approvals Database](#). The alternative S19A products may differ from the Australian registered product (Bicillin L-A). A comparison of the products/formulations is available in **Table 1** (at the end of this fact sheet).

The approved indications, dose specifications (including for special populations), warnings and precautions and side effect information may vary across the products. Full details are found in the Product Information (PI) or Summary of Product Characteristics (SmPC) for each of the S19A products according to the country of registration. This information is appropriate at the time of initial renewed product registration.

For the recommended dosing information for the approved indications, prescribers are referred to the Australian PI for Bicillin L-A benzylpenicillin tetrahydrate 1,200,000 units / 2.3 mL suspension for injection, pre-filled syringe with needle. Clinicians are expected to use their clinical judgement supported by the most recent evidence-based information to ensure safe and quality use of the products.

Safety and suitability considerations

There are safety considerations due to differences between Bicillin L-A and the **S19A alternatives**. The additional requirement for reconstitution with a diluent, and need for immediate administration may make these alternative products less suitable than pre-filled syringes for use in some patient cohorts.

The need to reconstitute the **S19A alternatives** prior to administration, and a larger volume for administration, should be considered as part of conserving supply of available benzathine benzylpenicillin (Bicillin L-A) prefilled syringes for paediatric patients.

Lentocilin S 1200 (Portugal) contains a diluent of 1.5% lidocaine solution for injection. Caution is recommended in some patient groups if lidocaine is used as a diluent.

Alternatively, water for injection may be used to reconstitute Lentocilin S 1200. Note: Lidocaine 1.5% is a Schedule 4 medicine and requires a separate prescription in addition to that for Lentocilin S 1200.

The **same safety and suitability considerations** should be applied to any alternative brands of benzathine benzylpenicillin that might be sourced via the SAS but not approved by the TGA under S19A.

Practice points

The following practice points are recommended to support clinical decision-making around the use of benzathine benzylpenicillin:

1. **Confirm the need** to use an antibiotic.
2. **Conserve** benzathine benzylpenicillin (Bicillin L-A) **prefilled syringes** for patient cohorts where the **S19A alternatives** may not be suitable (for example, in paediatric patients, including neonates, where the larger volume should be determined if appropriate for administration).
3. **Seek advice** from local Infectious Diseases experts and/or the Therapeutic Guidelines: Antibiotic (including the [Antibiotic prescribing in primary care: summary table](#)) for **alternative agents** if Bicillin L-A pre-filled syringes are unavailable and the S19A alternatives are unsuitable.

Useful resources

- Therapeutic Goods Administration (TGA) [Medicine Shortage Reports Database](#).
- Therapeutic Guidelines Antibiotic. [Antibiotic prescribing in primary care summary table](#).
- Australian Commission on Safety and Quality in Health Care [general information for prescribers and pharmacists](#) on how to manage shortages of antimicrobials in acute and primary healthcare settings.
- National Centre for Antimicrobial Stewardship [Medication Shortage Fact Sheets](#) provide information about prescribing choices and alternatives for common infections.
- [Therapeutic Guidelines](#). Melbourne: Therapeutic Guidelines Limited.
- [Australian Medicines Handbook](#). Adelaide: Australian Medicines Handbook Pty Ltd.
- The RHD Australia [Guidelines for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease 3rd Edition](#).
- Australasian Society of Infectious Diseases (ASID) guidelines: [Management of perinatal infections 3rd Edition](#).
- Australian Commission on Safety and Quality in Health Care [Principles for safe selection and storage of medicines](#) guidance on risk reduction strategies for safe selection and storage of medicines.
- Australian Commission on Safety and Quality in Health Care [guidance on conserving medicines within a focus on medicines shortages](#).
- Australian Commission on Safety and Quality in Health Care [information on antibiotic shortages for Aboriginal and Torres Strait Islander consumers](#).
- Australian Commission on Safety and Quality in Health Care [general information for clinicians working in the Aboriginal and Torres Strait Islander health sector](#).

For more information

Please visit: TGA [Medicine Shortage Reports Database](#) or contact the Commission at MedSafety@safetyandquality.gov.au.

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Safety considerations during Benzathine benzylpenicillin (Bicillin L-A) supply disruption

Table 1 Comparison of the ARTG listed 1,200,000 unit product and the S19A alternatives

	ARTG-listed product	S19A alternative (Portugal)	S19A alternative (UK)	S19A alternative (Spain)	Safety considerations
Brand and image of outer packaging	Bicillin L-A (Pfizer) 	Lentocilin S 1200 (available from Neon Healthcare) 	Brancaster Pharma (available from Pro Pharmaceuticals Group Pty Ltd) 	Benzetacil (available from Phero Pharma Pty Ltd) 	The Principles for safe selection and storage of medicines should be applied given that the storage location will differ. The S19A alternatives are not stored in the fridge and could inadvertently be placed on a shelf adjacent to similar looking outer packaging. Risk reduction strategies may need to be considered to ensure differentiation from other similar looking packaging. For example, storing in a separate location from other injectable medicines.

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Active ingredient and strength	Benzathine benzylpenicillin tetrahydrate 1,200,000 units	Benzathine benzylpenicillin 1,200,000 units	Benzylpenicillin benzathine 1,200,000 units	Benzylpenicillin benzathine 1,200,000 units	The active ingredient name on the S19A alternatives is expressed differently. Benzathine benzylpenicillin tetrahydrate and benzylpenicillin benzathine are synonyms. The Principles for safe selection and storage of medicines should be applied – for example, when selecting from a drop down menu within prescribing and dispensing systems.

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Appearance and formulation	White fluid suspension in a pre-filled syringe 	Powder (white/almost white) and solvent (clear, practically colourless) for suspension for injection 	Powder (white/off-white) for suspension for injection  The image is a vial of powder for suspension Reconstitution may be undertaken with water for injection (WFI) or injectable lidocaine solution 1% (not supplied)	Powder (white/almost white) and solvent (clear, colourless) for suspension for injection  Once the vial has been reconstituted with the contents of the solvent ampoule, a white or almost milky white suspension is obtained	The S19A alternatives, differ from the Australian registered product in presentation. The S19A alternatives require reconstitution prior to administration by: • Drawing up the recommended volume and diluent for the product using a recommended gauge needle and adding this to the vial containing the powder • Agitating the suspension carefully for at least 20 seconds until a homogeneous suspension is obtained. The S19A alternatives must be administered immediately once reconstituted.

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Volume required to administer 1,200,000 units dose	2.3 mL	4mL (plus powder displacement volume)	3.5 mL diluent (WFI) + powder displacement volume (results in a final volume of approximately 4.5 mL)	4.8mL (Final volume once the vial has been reconstituted with 4mL of water)	The final volume of both S19A alternatives is approximately double that of the ARTG-listed product. This has implications particularly in paediatrics. The use of a local anaesthetic, such as lidocaine 1.5% (Portugal) or 1% (UK), in place of water for injection (WFI), will potentially reduce pain at the injection site. See product information relevant to each product.
Consumer medicines information (CMI)	Access the Australian CMI here	Access to TGA guidance here	Access the UK leaflet here	The CMI is not publicly available in English, contact Phero Pharma for access.	The medicines information leaflets for the S19A alternatives contain similar information but are not TGA approved.

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Product Information (PI)	Access the Australian PI here	Access to TGA guidance here <i>Each LENTOCILIN S 1200 product is required to be packaged with an English language product information leaflet (either as a package insert or included alongside). If additional copies of this product information are required, please contact the section 19A approval holder, Neon Healthcare Pty Ltd, on (02) 7255 8455 or via office@neonhealthcare.com.au.</i>	Access the UK Summary of Product Characteristics (SmPC) here	The PI is not publicly available in English, contact Phero Pharma for access.	The product information for the S19A alternatives contain similar information but are not TGA approved.
Labelling	English	Portuguese	English	Spanish	The active ingredient is in English. However, the labelling for the S19A alternative from Portugal and Spain is in Portuguese and Spanish, respectively
Reconstitution requirements	Reconstitution not required. The suspension for injection is already in a prefilled for single use only .	The suspension for injection must be reconstituted with diluent before administration.	The suspension for injection must be reconstituted with 3.5 mL diluent before administration.	The suspension for injection must be reconstituted with 4mL solvent before administration.	The S19A alternatives must be reconstituted using aseptic technique .

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Needle gauge recommended for use in reconstitution and administration	21 gauge	18 gauge	20-22 gauge	20 gauge	If clogging occurs, replace the needle with a new needle of same (or greater) diameter. The needle gauge recommended for the S19A alternative from Portugal is lower than that commonly used for administration. Assess suitability for clinical use.
Route of administration	For deep intramuscular (IM) injection only				Refer to local clinical practice guidelines on appropriate administration technique for deep IM injection in conjunction with full details on method of administration for each product including specific instructions for paediatric patients (including neonates).

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Storage conditions	2 to 8 degrees Celsius* (Refrigerate, do not freeze) <i>[*Storage at 30°C, is allowed for a single period of 2 months prior to batch expiry.]</i>	Below 25 degrees Celsius	Below 25 degrees Celsius	In a dry place	The Principles for safe selection and storage of medicines should be applied given that the storage location of the S19A alternatives will differ.
Additional excipients	Sodium citrate; soy lecithin [#] ; carmellose sodium; povidone; and preservatives: methyl hydroxybenzoate propyl hydroxybenzoate	Sodium citrate, lecithin [#] and polysorbate 80	Soy lecithin [#] ; polysorbate 80; sodium citrate; carmellose sodium; and povidone	Soy lecithin [#] ; Tween 80; sodium citrate (E-331)	The list of excipients within the S19A alternatives , differ from the Australian registered product. <i>[#]The presence of excipients such as soy lecithin should be considered, especially for consumers with a soy or peanut allergy.</i>

	ARTG-listed product	<u>S19A alternative (Portugal)</u>	<u>S19A alternative (UK)</u>	<u>S19A alternative (Spain)</u>	Safety considerations
Included solvent	Nil	Lidocaine hydrochloride 1.5% solution	Water for injection	Water for injection	Caution is recommended in some patient groups if lidocaine 1.5% is used as the solvent. Alternatively, water for injection may be used to reconstitute Lentocilin S 1200. Note: Lidocaine 1.5% is a Schedule 4 medicine and requires a separate prescription in addition to that for Lentocilin S 1200.
Doses per pack	10 (individual pre-filled syringes)	1 x vial of powder for suspension 1 x glass ampoule containing lidocaine 1.5%	1 x vial of powder for suspension	1 x vial of powder for suspension 1 x glass ampoule containing water for injection	