

26 October 2023

Shortage of BICILLIN L-A benzathine benzylpenicillin tetrahydrate 1,200,000 Units / 2.3 mL suspension for injection pre-filled syringe with needle (AUST R 147169) and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*

Dear Healthcare Professional,

The Australian registered medicine **BICILLIN L-A benzathine benzylpenicillin tetrahydrate 1,200,000 Units / 2.3 mL suspension for injection pre-filled syringe with needle (AUST R 147169)** sponsored by Pfizer Australia is in short supply.

ORSPEC Pharma has arranged the supply of an alternative product **Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection (Brancaster Pharma, UK)** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **30 March 2024** for the following indication(s):

Intramuscular benzathine benzylpenicillin is indicated in the treatment of infections due to penicillin-sensitive micro-organisms that are susceptible to the low and very prolonged serum levels common to this particular dosage form. Therapy should be guided by bacteriological studies (including sensitivity tests) and by clinical response.

The following infections will usually respond to adequate dosage of intramuscular benzathine benzylpenicillin:

- *Streptococcal infections (Group A - without bacteraemia). Mild-to-moderate infections of the upper respiratory tract (e.g., pharyngitis). Venereal infections - Syphilis, yaws, bejel and pinta.*

Medical conditions in which benzathine benzylpenicillin therapy is indicated as prophylaxis:

Rheumatic fever and/or chorea - Prophylaxis with benzathine benzylpenicillin has proven effective in preventing recurrence of these conditions. It has also been used as follow-up prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.

Please note: CONTAINS SOYA LECITHIN

Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection (Brancaster Pharma, UK) should not be used in patients allergic to peanut or soya.

Prior to dispensing and administration, healthcare professionals should determine if this product is suitable for the patient.

Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection (Brancaster Pharma, UK) is registered in the United Kingdom and is identical in active ingredient and strength to the Australian registered product.

The two products differ in dose form, presentation, storage conditions and excipient ingredients as outlined in the table below.

	ARTG Product BICILLIN L-A benzathine benzylpenicillin tetrahydrate 1,200,000 Units / 2.3 mL suspension for injection pre- filled syringe with needle (AUST R 147169)	S19a Approved product Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection (Brancaster Pharma, UK)
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 solvent
Storage conditions	Store at 2 to 8°C. Refrigerate, do not freeze.	This medicinal product does not require any special storage conditions.
Excipient Ingredients	<ul style="list-style-type: none"> - Sodium citrate - Water for injections - Lecithin - Carmellose sodium - Povidone - Methyl hydroxybenzoate - Propyl hydroxybenzoate 	<u>Powder</u> <ul style="list-style-type: none"> - Soya lecithin - Polysorbate 80 - Carmellose sodium - Sodium citrate, anhydrous - Povidone <u>Solvent</u> <ul style="list-style-type: none"> - Water for injections

For the preparation and administration instructions, please refer to the attached UK Product Information for **Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection (Brancaster Pharma, UK)**.

For the recommended dosing information for the approved indications, please refer to the Australian Product Information for **BICILLIN L-A benzathine benzylpenicillin tetrahydrate 1,200,000 Units / 2.3 mL suspension for injection pre-filled syringe with needle (AUST R 147169)** available at <https://www.ebs.tga.gov.au/>

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection (Brancaster Pharma, UK)** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,



Deon Scheepers
Managing Director
ORSPEC Pharma