8 March 2024

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 **EXTENCILLINE benzathine benzylpenicillin 1.2 Million IU, powder and solvent for suspension for IM injection (France),** 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 September 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

EXTENCILLINE benzathine benzylpenicillin 1.2 Million IU, powder and solvent for suspension for IM injection (France) 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.

EXTENCILLINE benzathine benzylpenicillin 1.2 Million IU, powder and solvent for suspension for IM injection (France) is registered in the France and therefore all labelling is in French. It 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** EXTENCILLINE benzathine benzylpenicillin 1.2 Million IU, powder and solvent for suspension for IM injection (France)
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 product does not require any special storage conditions.
Excipient Ingredients	- Sodium citrate - Water for injections - Lecithin - Carmellose sodium - Povidone - Methyl hydroxybenzoate - Propyl hydroxybenzoate	Powder - Soya lecithin - Carmellose sodium - Sodium citrate, anhydrous - Povidone Solvent - Water for injections

For the preparation and administration instructions, please refer to the attached translated Product Information for **EXTENCILLINE benzathine benzylpenicillin 1.2 Million IU, powder and solvent for suspension for IM injection (France).**

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 **EXTENCILLINE benzathine benzylpenicillin 1.2 Million IU, powder and solvent for suspension for IM injection (France)** 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