Preparation and Dosing of Long-acting S19A Benzathine Benzylpenicillin BRANCASTER® Product

CAUTION: Seek medical advice before using either product in people with soya bean and peanut allergies.

This guideline has been prepared in collaboration with NT Health, Menzies School of Health Research, and National Aboriginal Community Controlled Organisations – December 2023

There is a national shortage of Bicillin LA® premix syringes provided by Pfizer (600,000 Units per 1.17 mL and 1,200,000 Units per 2.3 mL benzathine benzylpenicillin G (BPG)). An alternative long-acting BPG product is available for use in Australia from Brancaster Pharma® supplied by Orspec.

Bicillin LA premix (Pfizer) syringe

Brancaster vial of powder for suspension

The BRANCASTER® product is available from hospitals and pharmacies. Each box contains:

- 1 vial of benzathine benzylpenicillin G powder (1,200,000 units)
- 1 ampoule of Water for Injection (5mL)

PREPARATION OF THE BRANCASTER® POWDER FOR SUSPENSION

3.5mL of Lidocaine 1% OR 3.5mL of water for injection should be used to dilute the powder.

- The use of lidocaine hydrochloride as a diluent does not change the concentration of benzathine benzylpenicillin G and can significantly reduce the pain of injection.
- Reconstitute the powder into a suspension with either the 3.5mL of Lidocaine 1% **OR** 3.5mL of water for injection and carefully shake for at least 20 seconds until a smooth suspension is obtained.
- Any bubbling of the solution should subside after about 30 seconds.
- The product should be administered as a **deep intramuscular injection** immediately after reconstituting the suspension. The suspension for injection is intended for single use only.
- For part-doses transfer the volume of the dose required into a new syringe and discard remaining suspension.[1]
- A total volume of 5mL is the maximum that can be injected into a muscle in a single injection.
  - benzathine benzylpenicillin G 1,200,000 units of powder for suspension reconstituted with 3.5mL of diluent will give a total approximate volume of 4.5mL and therefore can be injected into a single injection site (where clinically appropriate).
  - In general, a needle of a diameter of at least 700µm (needle gauge: 22, 21 or 20) for intramuscular injection is recommended. [2]
  - The final total volume after reconstitution may vary and the volumes recommended are based on a mid-range of 4.5mL total volume with an accepted variance within the therapeutic range.

KEY MESSAGES ABOUT THE BRANCASTER® PRODUCT

It contains the same medication and dose as the Pfizer Bicillin LA® premix syringe product.

The dose remains the same, but the volume needed to be administered will be different.

It should be used for all conditions that require benzathine benzylpenicillin G

It does not need to be stored in the fridge (so does not need to be warmed prior to administration).

Patients with acute rheumatic fever and rheumatic heart disease still require injections every 21 to 28 days.

Patients receiving this product should be reassured about the following:

- it is safe for people of all ages.
- it is safe to use during pregnancy and breastfeeding.
- it is the same medicine and has the same therapeutic effect (it works as well) as the Bicillin LA® product.

Both Bicillin L-A and the Brancaster product both contain soy lecithin. Seek medical advice before commencing, or continuing, treatment with either product in patients with a peanut or soy allergy.

For administration of any intramuscular injection, it is recommended that patients are monitored for immediate adverse reactions, for example, fever, rash, vomiting or shortness of breath.

For more information about managing intramuscular injection pain and distress visit

https://www.rhdaustralia.org.au/arf-rhd-guidelines

DOSING AND FREQUENCY – BRANCASTER PRODUCT

RECOMMENDED DOSING AND FREQUENCY FOR THE FOLLOWING CONDITIONS HAVE NOT CHANGED.

Dilute with 3.5 mL of 1% Lidocaine **OR** 3.5 mL of water for injection (not 5 mL)

PRIMARY PREVENTION OF ACUTE RHEUMATIC FEVER [3] (treatment of skin sores and sore throat in high-risk people)			
INDICATION	**DOSE REQUIRED**	**VOLUME REQUIRED**	**FREQUENCY**
Child: Less than 10kg	450,000 units	Administer **1.8mL** of the total reconstituted volume	Once
10kg to less than 20kg	600,000 units	Administer **2.4mL** of the total reconstituted volume	
20kg or more	1,200,000 units	Administer the **total** reconstituted volume	
Adult: 20kg or more	1,200,000 units	Administer the **total** reconstituted volume	
SECONDARY PREVENTION OF ACUTE RHEUMATIC FEVER. [3]			
All people: Less than 20 kg	600,000 units	Administer **2.4mL** of the total reconstituted volume.	Every 21 to 28 days
20kg or more	1,200,000 units	Administer the **total** reconstituted volume	
TREATMENT FOR SYPHILIS (Adults) [4, 5]			
Infectious phase If known to be less than 2 years (adult)	2,400,000 units	Administer **two** reconstituted vials across two injection sites (Administer the **total** reconstituted volume of each vial)	Once
Latent or unknown phase If unknown duration or known to be more than 2 years (adult)	2,400,000 units	Administer **two** reconstituted vials across two injection sites (Administer the **total** reconstituted volume of each vial)	Once a week for 3 weeks
TREATMENT FOR SYPHILIS (Only for low risk/asymptomatic neonates, as per State/Territory guidelines) NOTE: For babies born with congenital syphilis (who require intravenous benzyl penicillin) and for older babies, consult a specialist in Paediatrics or Infectious Diseases.			
All neonates	50,000 units/kg	Administration volume must be calculated based on weight of child and the total reconstituted volume measured.	Once

NOTE The final total volume after reconstitution may vary and the volumes recommended are based on a mid-range of 4.5mL total volume with an accepted variance within the therapeutic range.

ALL INTRAMUSULAR INJECTIONS SHOULD BE ADMINISTERED IN LINE WITH LOCAL INJECTION PROCEDURES AND PROTOCOLS

REFERENCES

[1] Society of Hospital Pharmacists of Australia. (2023) The Australian Injectable Drugs Handbook; 9th Edition. Health Communication Network. Accessed via NT Health Library

[2] Brancaster Pharma Limited. 2023. Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection Healthcare Professionals (SmPC). Accessed via: https://www.medicines.org.uk/emc/product/11043/smpc#gref

[3] RHDAustralia (ARF/RHD writing group). The 2020 Australian guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (3.2 edition, March 2022); 2020

[4] Remote Primary Health Care Manuals. (2022). *CARPA Standard Treatment Manual (8th edition)*. Alice Springs, NT: Flinders University

[5] Queensland Health, Royal Flying Doctor Service (Queensland Section). Primary Clinical Care Manual. 11th ed. Cairns (AU): Office of Rural and Remote Health, Queensland Government; 2022.