

25 January 2022

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RE: Shortage of ONCOTICE BCG 5 hundred million CFU powder for injection vial (AUST R 59912) and alternative supply arrangement under Section 19A of the Therapeutic Goods Act.

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of the Australian registered **ONCOTICE BCG 5 hundred million CFU powder for injection vial (AUST R 59912)**, LINK has arranged the supply of an alternative product. LINK can supply **BCG Culture SSI BCG 30 mg/vial (AJ Vaccines)**.

BCG Culture SSI BCG 30 mg/vial (AJ Vaccines) is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **31 January 2024**

BCG Culture SSI BCG 30 mg/vial (AJ Vaccines) is approved for use under Section 19A for the following indication:

Treatment of primary or recurrent carcinoma in situ (CIS) of the urinary bladder. Intravesical BCG is also used after transurethral resection for the prevention of recurrence of high grade and/or relapsing superficial papillary transitional cell carcinoma of the urinary bladder (viz papillary carcinoma stage TA [grade 2 or 3] or T1 [grade 1, 2, or 3]). Intravesical BCG is only recommended for stage TA grade 1 tumours, when there is judged to be a high risk of tumour recurrence.

BCG Culture SSI BCG 30 mg/vial (AJ Vaccines) is labelled in English and contains an English language package insert.

Please note the following information regarding differences between **ONCOTICE BCG 5 hundred million CFU powder for injection vial (AUST R 59912)** and **BCG Culture SSI BCG 30 mg/vial (AJ Vaccines)**, supplied under section 19A (referred as the S19A product below). The Australian registered product and s19A product are derived from different substrains of *Mycobacterium bovis* BCG. Therefore, the recommended therapeutic dose and potency are not equivalent:

	ONCOTICE BCG 5 hundred million CFU powder for injection vial (AUST R 59912)	BCG Culture SSI BCG 30 mg/vial (AJ Vaccines) (S19A Product)
Strength	Vial contains $2-8 \times 10^8$ CFU Tice™BCG (strain)	Vial contains Mycobacterium bovis (BCG) Danish strain 1331, (approx. 2.5×10^8 CFU 30 mg)/vial
Pack Size	One or three glass vials	Four glass vials
Dosage	Each instillation comprises $2-8 \times 10^8$ CFU the contents of one reconstituted and diluted vial of OncoTICE suspended in physiological saline (0.9% sodium chloride) up to a total volume of 50 mL as indicated above.	The required dose of BCG CULTURE SSI (normal dose (120 mg) = 4 reconstituted vials) is resuspended in 50 ml sterile saline, (preservative-free 0.9% NaCl), in a sterile area using aseptic technique during the entire procedure.
Storage Reconstituted Product	In-use stability of the reconstituted product has been demonstrated for 2 hours at 2-8°C protected from light.	Store in a refrigerator (2°C – 8°C). The resuspended solution may be kept for up to four hours, protected from light.

Healthcare Professionals are advised to refer to the S19A product information leaflet for information regarding reconstitution and dosage instructions of **BCG Culture SSI BCG 30 mg/vial (AJ Vaccines)**.

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 **BCG Culture SSI BCG 30 mg/vial (AJ Vaccines)** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered intravesical BCG.

Yours sincerely,

A. Sharma

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Medicine Access Associate