

18th October 2023

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.

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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 **VESICULTURE BCG 30mg/vial powder for bladder irrigation (AJ Vaccines)** registered in Denmark.

VESICULTURE BCG 30mg/vial powder for bladder irrigation (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 **31st January 2026**

VESICULTURE BCG 30mg/vial powder for bladder irrigation (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.

VESICULTURE BCG 30mg/vial powder for bladder irrigation (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 **VESICULTURE BCG 30mg/vial powder for bladder irrigation (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)	VESICULTURE BCG 30mg/vial powder for bladder irrigation (AJ Vaccines) (S19A Product)
Strength	Vial contains 2-8 × 10 ⁸ CFU Tice™BCG (strain)	Vial contains Mycobacterium bovis (BCG) Danish strain 1331, (approx. 2.5 x 10 ⁸ CFU 30 mg)/vial
Pack Size	One or three glass vials	Four glass vials
Dosage	Each instillation comprises 2-8 × 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 VesiCulture BCG (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 **VESICULTURE BCG 30mg/vial powder for bladder irrigation (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 **VESICULTURE BCG 30mg/vial powder for bladder irrigation (AJ Vaccines)** should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Any product complaints regarding **VESICULTURE BCG 30mg/vial powder for bladder irrigation (AJ Vaccines)** should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation.
For further information, please contact LINK on 1800 161 060 or email

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,

Anita Sharma

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