

29 Jan 2022



RE: Shortage of NAVELBINE vinorelbine tartrate 50mg/5mL (AUST R 62248) and NAVELBINE vinorelbine tartrate 10mg/mL (AUST R 62246) 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 Australian registered **NAVELBINE vinorelbine tartrate 50mg/5mL (AUST R 62248)** and **NAVELBINE vinorelbine tartrate 10mg/mL (AUST R 62246)**, LINK has arranged the supply of an alternative product, **Vinorelbine Injection USP (Sagent)** registered and marketed in the USA. This product is available in both a **10mg/mL** injection and a **50mg/5mL** injection.

Vinorelbine Injection USP (Sagent) 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 May 2022.

Vinorelbine Injection USP (Sagent) 10mg/mL and 50mg/5mL are indicated for:

The treatment of advanced breast cancer after failure of standard therapy, as a single agent or in combination; and as first line treatment for advanced non-small cell lung cancer, as a single agent or in combination.

It is also indicated for the treatment, in combination with cisplatin, of patients with completely resected non-small cell lung cancer of stage IB or greater.

The s19A approved US product is identical in active ingredient, strength, and excipient ingredients to the Australian registered product and is labelled in English.

Please refer to the Australian Product Information for **NAVELBINE vinorelbine tartrate 50mg/5mL and NAVELBINE vinorelbine tartrate 10mg/mL** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Vinorelbine Injection USP (Sagent) 10mg/mL and 50mg/5mL**.

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 **Vinorelbine Injection USP (Sagent) 10mg/mL and 50mg/5mL** 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.

Please contact Link Healthcare Customer Service for further information.

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 **NAVELBINE vinorelbine tartrate 50mg/5mL and NAVELBINE vinorelbine tartrate 10mg/mL**.

Yours sincerely,

A. Sharma

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Medicine Access Associate