Direct Healthcare Professional Communication

May 2023

VINORELBINE, NAVELBINE 50MG/5ML & 10MG/1ML SOLUTION FOR INJECTION IN A VIAL, Introduction Of An Undesirable Effect: Acute Respiratory Distress Syndrome

Dear Healthcare Professional,

Pierre Fabre, in agreement with The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- The product information for Navelbine 50mg/5ml & 10mg/ml solution for injection in a vial will be updated to include a new undesirable effect 'acute respiratory distress syndrome (ARDS)'.
- This information is being sent in agreement with the EPVC.

Further information on the safety concern and the recommendations

Vinca alkaloid-induced pulmonary toxicity has been widely described in the literature, and its clinical manifestations are well known to practitioners. Mechanisms of this toxicity can be due to direct cytotoxic lesions caused by antineoplastic agents or due to indirect toxicity i.e. hypersensitivity reaction with a drug-specific antibody or a T-cell response that can also cause lung damage.

Vinorelbine-induced lung toxicity may be driven by a primarily immune-mediated mechanism (indirect toxicity) and could be multifactorial i.e. underlying disease with pulmonary metastasis, previous or concomitant treatments (chemotherapy and radiotherapy) and lung surgery, promoting lesions such as infectious or interstitial

Analysis of case reports confirmed that ARDS described in patients treated with vinorelbine was most often secondary to either severe infection or interstitial lung disease in patients with predisposing factors. Of note, severe infection and interstitial lung disease are already included as adverse drug reactions in the SPC of Navelbine.

ARDS is a serious consequence which can be fatal regardless of it its mechanism (direct or indirect lung toxicity). The addition of ARDS into the SPC Navelbine is deemed an important new information for practitioners through this DHPC Letter to raise their attention.

The SPC of Navelbine 50mg/5ml & 10mg/ml solution for injection is being amended to include this new information."

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ARDS was not initially identified from clinical trials. Based on post-marketing experience, the frequency could not be precisely estimated and is determined "not known" in the SPC.
As per the latest European periodic safety update assessment by health authorities issued in December 2022 taking into consideration the newly added adverse reaction ADRS for vinorelbine, the risk-benefit balance of medicinal products containing the active substance vinorelbine remains positive and unchanged.

Further information

Navelbine IV is indicated in:
• non-small cell lung cancer
• metastatic breast cancer

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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