Australia: New warning on hepatotoxicity risk for Veoza (fezolinetant)

The Therapeutic Goods Administration (TGA) announces advice to give patients and recommendations for hepatic monitoring.

Summary
New warnings on hepatotoxicity risk and monitoring recommendations have been added to the Product Information for Veoza (fezolinetant).

We undertook a review after the pharmaceutical company Astellas notified us of an analysis of their global safety database, including post-marketing cases of hepatotoxicity. We then worked with them to update the Australian Product Information.

Fezolinetant is used to treat moderate to severe vasomotor symptoms associated with menopause. These symptoms include sudden feelings of warmth (hot flashes) and sweating (night sweats) that occur when the body's temperature regulation system malfunctions.

What health professionals should do
Be alert to the new advice as described in 'Updates to the PI' below.

Advise patients to discontinue Veoza immediately and seek medical attention, including hepatic laboratory tests, if they experience signs or symptoms that may suggest hepatotoxicity. Such symptoms include new-onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale faeces, dark urine or abdominal pain.

Perform follow-up evaluation of hepatic function monthly for the first 3 months after initiating Veoza, then at 6 months and 9 months, and thereafter periodically based on clinical judgement.

Updates to the PI
The following updates have been made to the Australian Product Information:

4.2 Dose and method of administration

Perform baseline hepatic laboratory tests to evaluate for hepatic function and injury [including serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), serum alkaline phosphatase (ALP) and serum bilirubin (total and direct)] before initiating treatment with Veoza. Do not start Veoza if ALT or AST is ≥ 2 x ULN or if the total bilirubin is ≥ 2 x ULN for the evaluating laboratory. While using Veoza, perform follow-up hepatic laboratory tests monthly for the first 3 months, at 6 months and 9 months after initiation of therapy.

Advise patients to discontinue Veoza immediately and seek medical attention including hepatic laboratory tests if they experience signs or symptoms that may suggest liver injury (see section 4.4 Special warnings and precautions for use).

4.4 Special warnings and precautions for use

In the post-marketing setting, cases of serious but reversible hepatotoxicity have been reported within 40 days of treatment. Patients have experienced transaminase elevations (greater than 10 times the ULN) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP), sometimes associated with signs or symptoms such as fatigue, pruritus, jaundice, dark urine or abdominal pain.

Evaluate hepatic function (ALT, AST, ALP and bilirubin) before initiating therapy. Do not initiate Veoza if ALT or AST is equal to or exceeds 2 times the ULN or if the total bilirubin is elevated (e.g., equal to or exceeds 2 times the ULN).

Patients should discontinue Veoza immediately and seek medical attention, including hepatic laboratory tests, if they experience signs or symptoms that may suggest hepatotoxicity such as new-onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale faeces, dark urine or abdominal pain.

Perform follow-up evaluation of hepatic function monthly for the first 3 months, at 6 months and 9 months after initiating Veoza, and thereafter periodically based on clinical judgement.

Discontinue Veoza if:

- transaminase elevations are greater than 5 times the ULN
- transaminase elevations are greater than 3 times the ULN and the total bilirubin level is greater than 2 times the ULN.

Monitoring of liver function tests should continue until they have normalised, and other causes of liver injury should be excluded.

Section 4.8 Adverse effects (undesirable effects)

Addition of the following adverse reactions:

- Aspartate aminotransferase (AST) increased with a frequency of common.
- Hepatotoxicity with a frequency of not known.

Description of selected adverse reactions:

Hepatotoxicity Serious cases of drug-induced hepatotoxicity occurred within 40 days of starting Veoza. Patients experienced elevated transaminases (up to 50 x ULN at peak elevation), elevated alkaline phosphatase (up to 4 x ULN at peak elevation) and bilirubin (up to 5 x ULN at peak elevation), coupled with symptoms of fatigue, nausea, pruritus, jaundice, pale faeces and dark urine. After discontinuation of Veoza, these abnormalities gradually resolved.

Adverse events reported to us

A search of our database of adverse event notifications on 17 September 2025 found a total of 14 reports for fezolinetant with any adverse event. Of these, there was 1 case of alanine aminotransferase increased, 1 case of liver function test increased and 1 case of liver function test abnormal.

Please refer to the following website in TGA for details:
http://www.tga.gov.au/news/safety-updates/new-warning-hepatotoxicity-risk-veoza-fezolinetant

In Hong Kong, Veoza Tablets 45mg (HK-68654) is currently a pharmaceutical product registered by Astellas Pharma Hong Kong Company Limited. It is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction with regard to fezolinetant.

Related news was previously issued by the United States Food and Drug Administration, European Medicines Agency and United Kingdom Medicines and Healthcare products Regulatory Agency, and was posted on the Drug Office website on 13 Sep 2024, 30 Nov 2024 and 11 Apr 2025. The current product insert of the locally registered Veoza already includes safety warnings on the risk of drug-induced liver injury and the recommended monitoring of liver function. The DH will remain vigilant on the safety update of the concerned drug issued by other overseas drug regulatory authorities.

Ends/Friday, Oct 17, 2025
Issued at HKT 16:30