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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

13 Apr 2026

Dear Healthcare Professionals,

Ontozry (cenobamate): New requirements for liver monitoring due to reports of severe liver injury

Your attention is drawn to the following European Medicines Agency (EMA)'s announcement that its Pharmacovigilance Risk Assessment Committee (PRAC) agreed on a direct healthcare professional communication to inform healthcare professionals that cases of severe liver injury with hepatic failure have been reported in patients treated with the medicine Ontozry. Most cases occurred when the medicine was used alongside other anti-seizure medications.

Prescribers are recommended to conduct liver function tests before starting treatment with Ontozry and throughout treatment.

They should carry out a prompt clinical evaluation and liver function tests in patients who have symptoms indicating liver injury, such as fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice.

Patients should be advised to immediately seek medical attention if they experience signs or symptoms suggesting liver injury.

If liver injury is suspected or detected, dose reduction or discontinuation of Ontozry should be considered, in line with the guidelines of the summary of product characteristics (i.e., unless required, avoid abrupt discontinuation to minimise the risk of rebound seizures).

Increased liver enzyme levels are already listed in Ontozry's product information as a common side effect (which may occur in up to 1 in 10 people).

Following its review of the cases, PRAC recommended adding liver injury as a rare side effect (which may occur in up to 1 in 1,000 people) to Ontozry's product information and

including warnings for patients and healthcare professionals.

Ontozry is a medicine for treating epileptic seizures starting in one specific part of the brain (focal seizures), including those that eventually spread to the whole brain (secondary generalisation). It is used as an add-on to other epilepsy medicines for adults with seizures that are not controlled despite having tried at least two other treatments.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7-10-april-2026

In Hong Kong, there are 9 registered pharmaceutical products containing cenobamate. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction with regard to cenobamate. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Clive CHAN)
for Assistant Director (Drug)