



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 April 2026

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7 – 10 April 2026

PRAC agrees on communication to healthcare professionals about cases of liver injury with epilepsy medicine

New safety information for healthcare professionals

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

PRAC agreed on a direct healthcare professional communication (DHPC) 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.

The DHPC for Ontozry will be forwarded to EMA's human medicines committee (CHMP). Once adopted, it will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the [Direct healthcare professional communications](#) page and in [national registers in EU Member States](#).