8 ottobre 2026

Ocrevus (ocrelizumab): New risk of drug-induced liver injury and recommendations on monitoring of liver function before and during treatment

Dear Healthcare professional,

Hoffmann-La Roche Ltd and Genentech in agreement with the European Medicines Agency (EMA) and the Italian Medicines Agency (AIFA) would like to inform you of the following:

Summary

- **Drug-induced liver injury, including severe and life-threatening cases, has been identified as a new risk for patients treated with Ocrevus.**
- **Liver function tests (LFTs) should be performed prior to initiating treatment with Ocrevus and prior to the second initial 300 mg infusion.**
- **Patients should be informed by treating physician about signs and symptoms of any hepatic injury during treatment, including but not limited to: new or worsening fatigue, anorexia, nausea, vomiting, right upper abdominal discomfort, dark urine or jaundice.**
- **Patients and caregivers should be advised to immediately seek medical attention if they experience signs or symptoms suggesting liver injury.**
- **LFTs should be performed promptly in any patient who reports symptoms that may indicate liver injury.**
- **If liver injury is confirmed, Ocrevus should be discontinued. Treatment should not be resumed unless a plausible alternative aetiology for the signs and symptoms of liver injury can be established.**

Background on the safety concern

Ocrevus is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. Ocrevus is indicated for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity. Ocrevus is approved as a twice-yearly 600 mg intravenous dose and a twice-yearly 920 mg subcutaneous dose.

As of 31 October 2025, an estimated total of 451,174 patients with MS have received Ocrevus across a combination of interventional clinical trials, pre-approval access programmes and

post-marketing experience. This corresponds to an estimated total cumulative exposure of more than 1,4 million patient-years.

A review of all available data concerning liver injury has concluded that Ocrevus is associated with a risk of drug-induced liver injury.

Temporal association: cases showed strong evidence of a temporal association to the first initial dose of ocrelizumab, with onset typically within one month (prior to and following the 2nd 300mg infusion at day 14).

The majority of cases were not serious but some were severe or life-threatening, with markedly elevated serum aminotransferases and total bilirubin. In a few instances, patients were temporarily placed on transplant lists, but liver injury resolved following treatment resulting in removal from transplant list.

The review of available data concerning liver injury did not identify a clear mechanism.

The product information will be updated to include information on this adverse reaction (frequency category: unknown) and measures to reduce the risk.