11 Jul 2025

Ocrevus® [Ocrelizumab 300 mg concentrate for solution for infusion (r-DNA origin) 300 mg/10 mL (30 mg/mL) in a single-dose vial]: Liver Injury with Ocrelizumab

Dear Healthcare professional,

Roche Products (India) Pvt. Ltd. would like to inform you of the following:

Summary

A recent review of data identified a case series presenting a pattern of clinically significant liver injury without findings of viral hepatitis, associated with the start of ocrelizumab treatment.

The purpose of this Dear Health Care Professional Letter is to inform you that:

1. Clinically significant liver injury without findings of viral hepatitis has been classified as an identified risk for ocrelizumab.
2. Liver function tests should be obtained prior to initiating treatment with ocrelizumab and signs and symptoms of any hepatic injury during treatment should be monitored.
3. Liver functional tests should include, at a minimum, serum aminotransferases, alkaline phosphatase, and bilirubin levels. These tests should be performed promptly in patients who report symptoms that may indicate liver injury.
4. If liver injury is present, ocrelizumab should be discontinued. If an alternative etiology is identified, treatment with ocrelizumab can be resumed only when the event has fully resolved.

Background on the safety concern

Ocrelizumab is approved for the treatment of patients with relapsing forms of multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS). Ocrelizumab is approved as a twice-yearly 600 mg intravenous infusion.

As of 31 March 2025, an estimated total of more than 420,000 patients with MS have received ocrelizumab across a combination of interventional clinical trials, pre-approval access programmes and post-marketing experience. This corresponds to an estimated 1,2 million patient years of total cumulative exposure.

Following a review of all available data concerning liver injury with ocrelizumab, a pattern of liver injury without findings of viral hepatitis has been identified in a case series which shows reasonable evidence of a temporal association with the first administration of ocrelizumab. The review also showed that, while liver function recovered within a period of up to 2 months, spontaneously or in response to standard symptomatic treatment, cases were clinically significant and could result in severe liver injury. In a few cases, patients were temporarily added to a transplant list.

Roche Products (India) Pvt. Ltd. is sending this communication to inform you that liver injury is now classified as an identified risk for ocrelizumab. These cases were infrequently reported mainly in the post-marketing setting and frequency cannot be accurately calculated.

Roche Products (India) Pvt. Ltd.

CIN - U74999MH1994PTC077533
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Prescriber action

Counsel patients about the risks and benefits of ocrelizumab. Physicians should inform patients that:

- clinically significant liver injury, without findings of viral hepatitis is a new identified risk for ocrelizumab.
- Liver function tests should be obtained prior to initiating treatment with ocrelizumab and signs and symptoms of any hepatic injury during treatment should be monitored.
- Liver functional tests should include, at a minimum, serum aminotransferases, alkaline phosphatase, and bilirubin levels. These tests should be performed promptly in patients who report symptoms that may indicate liver injury.
- If liver injury is present, ocrelizumab should be discontinued. If an alternative etiology is identified, treatment with ocrelizumab can be resumed only when the event has fully resolved.

Call for Safety / Adverse Event Reporting

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of Ocrevus® [Ocrelizumab 300 mg concentrate for solution for infusion] to us at +91-98201 637524 or india.drugsafety@roche.com

Company contact point

Should you have any questions or require additional information regarding the use of Ocrevus® [Ocrelizumab 300 mg concentrate for solution for infusion] to us at 1800-833-3374 or india.medinfo@roche.com

Yours sincerely,
Roche Products (India) Pvt. Ltd.

Signed by:
Sivabalan Sivanesan
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Director-Medical & Regulatory Affairs

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