

## Safety Alert

Jan 2025

### Ozanimod – risk of liver injury

EDA performs label update to include the following:

#### Special warnings and precautions for use

##### **Liver injury**

Clinically significant liver injury has occurred in patients treated with ozanimod in the post marketing setting. Signs of liver injury, including elevated serum hepatic enzymes and elevated total bilirubin, have occurred as early as ten days after the first dose. Severe liver injury may result in the need for a liver transplant

#### Undesirable Effects:

Hepatobiliary Disorders

Rare: Liver injury

#### **Background:**

##### Liver injury:

There are many different types of liver injuries with common process. From the beginning of disease, inflammation occurs in liver. With the inflammation sustains, it starts to hurt liver permanently. In the end stage of liver disease, the transformation of liver is irreversible and the normal function of liver could be hardly maintained.

#### Therapeutic Indication of Ozanimod

- Multiple sclerosis  
ozanimod is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.
- Ulcerative colitis  
ozanimod is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.

#### References:

EMA ([Click here](#))