

Safety Alert

July 2025

Olaparib – risk of drug-induced liver injury (DILI)

EDA performs label update to include the following:

Special warnings and precautions for use

Hepatotoxicity

Cases of hepatotoxicity have been reported in patients treated with olaparib. If clinical symptoms or signs suggestive of hepatotoxicity develop, prompt clinical evaluation of the patient and measurement of liver function tests should be performed. In case of suspected drug-induced liver injury (DILI), treatment should be interrupted. In case of severe DILI treatment discontinuation should be considered as clinically appropriate.

Undesirable effects

Hepatobiliary disorders

Not Known drug-induced liver injury (DILI)

Background:

Therapeutic Indication

- Ovarian cancer
- Breast cancer
- Adenocarcinoma of the pancreas
- Prostate cancer
- Endometrial cancer

Drug-induced liver injury (DILI)

Drug-induced liver injury (DILI) is an acute or chronic liver injury secondary to drugs or herbal compounds it is common and nearly all classes of medications can cause liver disease. Most cases of DILI are benign, and improve after drug withdrawal. It is important to recognize and remove the offending agent as quickly as possible to prevent the progression to chronic liver disease and/or acute liver failure.

References:

EMA ([Click here](#))