

Safety Alert

April 2025

Propofol –Risks of hepatitis and acute hepatic failure

EDA performs label update to include the following:

CLINICAL PARTICULARS

Undesirable effects

Hepatobiliary disorders:

Frequency not Known: Hepatitis, acute hepatic failure.

Background:

Therapeutic Indication

Propofol is a short-acting intravenous general anaesthetic for:

- Induction and maintenance of general anaesthesia,
- Sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia

Background on safety concern:

Acute liver failure is an uncommon condition in which rapid deterioration of liver function results in coagulopathy, usually with an international normalized ratio (INR) of greater than 1.5, and alteration in the mental status (encephalopathy) of a previously healthy individual. Acute liver failure often affects young people and carries a very high mortality.

References:

EMA ([Click here](#))