Consumer Update

July 2022

Ketamine risk of Biliary duct dilatation

EDA performs label update to include the following:

WARNINGS AND PRECAUTIONS section

Drug-Induced Liver Injury

Ketamine administration is associated with hepatobiliary dysfunction (most often a cholestatic pattern), with recurrent use (e.g., misuse/abuse or medically supervised unapproved indications). <u>Biliary duct dilatation</u> with or without evidence of biliary obstruction has also been reported with recurrent use. Obtain baseline LFTs, including alkaline phosphatase and gamma glutamyl transferase, in patients receiving ketamine as part of a treatment plan that utilizes recurrent dosing. Monitor those receiving recurrent ketamine at periodic intervals during treatment.

Background on the safety concerns

Ketamine is a general anesthetic indicated:

• As the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation .

- For the induction of anesthesia prior to the administration of other general anesthetic agents
- as a supplement to other anesthetic agents.

<u>References:</u>

- 1. FDA (Click here)
- 2. Health Canada (Click here)