



Direct Healthcare Professional Communication

September 2022

Ketamine- Risk of Biliary Duct Dilatation

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

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

Background information on the security concerns

Ketamine hydrochloride sterile solution for I.V / I.M injection in vial is recommended:

- As an anaesthetic agent for diagnostic and surgical procedures.
- For the induction of anaesthesia prior to the administration of other general anaesthetic agents.
- To supplement other anaesthetic agents.

Ketamine is increasingly used as a recreational hallucinogenic drug. Consumption may result in mood elevation and visual hallucinations with colorful vision and feelings of derealization (a weightless and out-of-body experience). These psychedelic experiences are usually referred to as 'trips'. There have been a growing number of reports on the use of recreational ketamine on a global scale.

Cases of biliary duct dilatation with or without evidence of biliary obstruction have been reported with ketamine recurrent use either due to misuse, abuse or use in medically supervised unapproved indications.

Ketamine-induced biliary dilatation is an acquired biliary tract disease caused by the abusive consumption of ketamine, which results in the fusiform dilatation of the common bile ducts (CBD) without obstructive lesions or dilatation of the intrahepatic biliary ducts. Possible manifestations of the underlying cholangiopathy include epigastric pain and impaired liver function. Severity of CBD dilatation appears to correlate with the duration of ketamine consumption and the condition has been reported to be reversible in abstinent patients.





Recommendations for Healthcare Professionals:

- Clinicians should obtain baseline liver function tests, including alkaline phosphatase and gamma glutamyl transferase, in patients receiving ketamine as part of a treatment plan that utilizes recurrent dosing.
- Clinicians should monitor patients receiving recurrent ketamine at periodic intervals during treatment.

References

FDA

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/016812s051lbl.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 - 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

