General Administration for Pharmaceutical Vigilance





جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للرعاية الصيدلية الإدارة العامة لليقظة الصيدلية

Direct Healthcare Professional Communication

Oct 2023

Ketamine: prolonged use leads to serious hepatic and uro-nephrological damage

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following **hepatic and uro-nephrological damage with prolonged use of ketamine**

Summary:

- An overall increase in the use of ketamine;
- an increase in the number of hepatobiliary (such as cholestasis or cholangitis) and uro-nephrological disorders (non-infectious cystitis, interstitial cystitis, acute renal failure, hydronephrosis), most often serious, after prolonged or repeated use of ketamine;
- off-label use, frequently in the context of prolonged use, mainly when taking in charge of chronic pain including fibromyalgia.
- respect the recommended dosages and limit exposure over time;
- monitor liver function closely (complete liver transaminases, GGT, ALP and bilirubin assessment) in the event of repeated or prolonged use; monitor renal function and urinary cytology closely in the event of repeated or prolonged use. The
- occurrence of hematuria constitutes a warning symptom for screening for urinary tract damage;
- the occurrence of hepatobiliary and/or uro-nephrological damage should suggest repeated use of ketamine in a medical or non-medical context (festive or sexual use chemsex practice).

Further information on the safety concern and the recommendations

Reminder of current prescription and delivery conditions:

Ketamine:

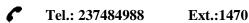
- o is a narcotic whose prescription is limited to 28 days, written in full on a secure prescription
- o is reserved for hospital use

21st Abdel-Aziz Al-Saud, Manial Al-Roda, Cairo

- can be administered by any doctor specializing in anesthesia-resuscitation or emergency medicine in cases where they intervene in an emergency situation or as part of a mobile medical assistance or medical repatriation structure.
- o In the case of home treatment, given the potential risk of abuse and misuse of ketamine, patients and caregivers must be informed of the need:
- o keep the ampoules in a locked, safe and secure place where other people cannot to access; return all unused ampoules to the pharmacy.







The Arab Republic of Egypt Egyptian Drug Authority

Central Administration for Pharmaceutical Care

General Administration for Pharmaceutical Vigilance





جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للرعاية الصيدلية الإدارة العامة لليقظة الصيدلية

Reference:

ANSM: https://ansm.sante.fr/informations-de-securite/ketamine-une-utilisation-prolongee-entraine-des-atteintes-graves-hepatiques-et-uronephrologiques

Call for reporting

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

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

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

QR Code:

Hotline: 15301







