



Direct Healthcare Professional Communication

November 2022

Propofol – Reminder of Instructions for Safe Use

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:

Summary:

- Propofol is for single use only.
- Opened containers must be disposed of after use.
- Any remaining residue of the content must be discarded and never reused by another patient.

Background on the safety concern

Propofol Indication:

- Propofol is approved for induction and maintenance of anesthesia in adults and children from 1 month.
- Sedation for diagnostic and surgical procedures in adults and children from 1 month
- Sedation of ventilated patients over 16 years of age in intensive care

Among other things; the following safety instructions (depending on the dosage form) must be strictly observed:

- Before use, the rubber membrane of the vial should be cleaned with medicinal alcohol.
- Propofol contains no antimicrobial preservatives and favors the growth of microorganisms.
- The emulsion must be drawn aseptically using a sterile syringe and infusion set immediately after breaking the seal of the vial.
- Administration must be started immediately.
- Both the medicinal product and the infusion set must be kept aseptic throughout administration.
- The duration of an undiluted propofol infusion from an infusion system must not exceed 12 hours, for diluted propofol infusions must not exceed 6 hours. After 12 hours or 6 hours; leftovers of propofol products must be discarded and the infusion system renewed.
- The contents of the vial, as well as any syringe or infusion set used, containing propofol is for single use for an individual patient only. Contents remaining after use must be discarded.

Failure to comply with these requirements result in serious side effects. Serious side effects are side effects that are fatal or life-threatening or, for example, require hospitalization





References

BASG

https://www.basg.gov.at/fileadmin/redakteure/06_Gesundheitsberufe/DHPC/2022/220713_Propofol.pdf

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

