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

Direct Healthcare Professional Communication

Aug 2023

Propofol: risk of sepsis when withdrawn multiple times from one container

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:

- Drugs containing propofol are only approved for single use in a single patient.
- Opened containers must be disposed of after use. Any remaining residues must be discarded and must not be reused under any circumstances.
- Aseptic technique should be used when removing propofol from a container.
- Failure to follow the recommendations for use can lead to life-threatening and fatal outcomes, including sepsis and death.

Further information on the safety concern and the recommendations

The contents of any vial, glass ampoule, syringe or infusion set containing propofol are for single patient use only. Contents remaining after application must be discarded.

Multiple withdrawal represents a medication error that is associated with significant risks for the patients concerned.

Medicines containing propofol are emulsions that do not contain preservatives and promote the growth of microorganisms. If handled non-aseptically or if the product is removed more than once, a strong growth of germs can occur within a short time.In the past, the use of microbially contaminated medicinal products containing propofol has repeatedly led to cases of sepsis, sometimes with a fatal outcome.

Therefore, emulsions containing propofol must be removed from a container under aseptic conditions: Before withdrawing from an ampoule or vial, the container must be disinfected. In the case of bottles, the stopper must also be disinfected.

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The emulsion must be drawn up aseptically into a sterile syringe and/or sterile infusion set immediately after opening.
Administration must be started immediately.
Both the medicinal product and the infusion set must be kept aseptic at all times during the infusion.

References:

https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RHB/2023/rhb-propofol.pdf?__blob=publicationFile

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

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