

SB TITCK 08.06.2023 PROPOFOL İLAÇ KULLANIM HATASI RISKI-ACIL GÜVENLİLİK KISITLAMASI_EN

Phone: (0 312) 218 30 00 Fax: (0 312) 218 34 60 E-mail: halkla.iliskiler@titck.gov.tr Website: <https://www.titck.gov.tr> Registered e-mail: titck@hs01.kep.tr 1 | 1

REPUBLIC OF TÜRKİYE MINISTRY OF HEALTH Turkish Medicines and Medical Devices Agency
08.06.2023 Number : E-24931227-510.01.04-1131468 Subject : Propofol/Medication Error/Urgent Safety Restriction

DOSSIER

Our Agency has evaluated the warning titled "Propofol – Medication errors that could potentially lead to life- threatening/fatal cases" published on the official website of the European Medicines Agency on 11 April 2023 regarding medication errors that lead to life-threatening and fatal sepsis cases with all medicines containing propofol, for which a link is provided in Annex2. You are required to add the statements in Annex1 to the primary and secondary packaging of the medicinal products in question licensed in Türkiye. You are kindly requested to submit the primary and secondary packaging of all propofol-containing medicines reflecting the aforementioned changes to the Authorised Drugs Unit for review within 15 days from the date of the announcement.

Dr. Asım HOCAOĞLU Agency President

Annex1: Union Association Announcement (1 page) Appendix2: https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-adopted-13-16-march-2023-prac-meeting_en.pdf signals-

Distribution: To: Pharmaceutical Industry Association of Türkiye Association of Researched-based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Türkiye Healthcare Products Association

This document is signed with a secure electronic signature. Document Verification Code: ZW56M0FyZ1AxM0FySHY3RG83ak1UZmxX Document Tracking Address: <https://www.turkiye.gov.tr/saglik-titck-ebys>

Söğütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA Phone: (0 312) 218 30 00 Fax: (0 312) 218 34 60 E-mail: halkla.iliskiler@titck.gov.tr Website: <https://www.titck.gov.tr> Registered e-mail: titck@hs01.kep.tr 2 | 1

REPUBLIC OF TÜRKİYE MINISTRY OF HEALTH Turkish Medicines and Medical Devices Agency

[The following statements should be included in the primary and secondary packaging of all propofol-containing medicines.]

• "For single-use in a single patient. There is a risk of sepsis in multiple use." • "Use immediately after opening."

This document is signed with a secure electronic signature. Document Verification Code: ZW56M0FyZ1AxM0FySHY3RG83ak1UZmxX Document Tracking Address: <https://www.turkiye.gov.tr/saglik-titck-ebys>