



Direct Healthcare Professional Communication

Feb 2023

Desflurane, SUPRANE, Introduction of 2 warnings in the updated leaflet

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:

- An update to the product leaflet for SUPRANE has been approved by the Egyptian Drug Authority (EDA), to add the following under “warnings and precautions section:
 - QTc prolongation

QTc prolongation, associated with torsade de pointes, has been reported.

Carefully monitor cardiac rhythm when administering SUPRANE to susceptible patients (e.g. patients with congenital Long QT Syndrome or patients taking drugs that can prolong the QT interval).

- Pediatric neurotoxicity

Published animal studies demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of these findings is not clear. However, based on the available data, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately three years of age in Humans

- Some published studies in children suggest that similar deficits may occur after repeated or prolonged exposures to anesthetic agents early in life and may result in adverse cognitive or behavioral effects. These studies have substantial limitations, and it is not clear if the observed effects are due to the anesthetic/sedation drug administration or other factors such as the surgery or underlying illness.
- Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions





regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Baxter sends the above-mentioned information in agreement with EDA.

Further information on the safety concern and the recommendations

The company is disseminating this letter to raise awareness regarding added warnings and precautions; as per Pharmacology department recommendations, until publishing the leaflet updated version.

Further information

SUPRANE is a general anesthetic, it is an inhalation agent which indicated for:

- Induction and/or maintenance of anesthesia in adults
- Maintenance of anesthesia in pediatric patients following induction with agents other than SUPRANE and intubation permit the desired daily dose to be administered slowly by intravenous drip over a 24 hour

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

