

Date: 19/07/2023

Propoven 1% (Propofol 1%), Clarification of Shelf-Life Stickers

Dear Healthcare Professional,

Fresenius Kabi in agreement with the Saudi Food and Drug Authority would like to inform you of important information for Propoven 1%:

Summary

- Propoven 1% is indicated for induction and maintenance of general anaesthesia.
- Propoven 1% recently got the approval for shelf-life extension from 24 months to 36 months and according to that, the outer packaging of Propoven 1% of batch number: 16RE4623, have stickers stating the expiry date 05/2025 while the inner label stating the expiry date 05/2024, the stickers were not applied in the inner label due to the small space and since the packaging is tightly closed, which ensures the safety of the product and its compliance with manufacturing specifications.
- The expiry date is 05/2025 (3 years Shelf life) for all quantities of Propoven 1% with batch numbers: 16RE4623.
- We are confirming that this concern is related to the mentioned batch numbers and the concern has been solved with our manufacturing facilities to avoid any inconvenience, so all other imported shipments of Propoven 1% are stating the correct shelf life (3 years) in the inner and outer labels.

Call for reporting

You can help provide more information on the safety of this medicine for National Pharmacovigilance Centre (NPC) by one of the following:

- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: <https://ade.sfda.gov.sa/>

Company contacts point

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