Fresenius Kabi USA

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December 20, 2022

Subject: Shelf-Life Extension: Etomidate Injection, USP, for intravenous use, 20mg/10mL (2mg/mL), and 40mg/20mL (2mg/mL)

Dear Healthcare Professional,

The U.S. Food and Drug Administration (FDA) issued approval for shelf-life extension of Fresenius Kabi Etomidate Injection, USP, for intravenous use from 18 months to 24 months based on available long term stability study data. The following Lot Numbers are currently available and have received the approval for shelf-life extension.

Providers that have the lot numbers in stock or receive inventory from these lot numbers will be able to use them through the corresponding new use dates to help with supply during the current Etomidate market shortage. FDA is not requiring that the identified lot numbers in the following table be relabeled with their new use dates. However, if replacement product becomes available during the extension period, then customers are expected to replace the lots and properly dispose of these lots as soon as possible.

Etomidate Injection, USP, for intravenous use					
NDC Unit of Sale	**NDC Unit of Use**	**Strength**	**Lot Number**	**Current Expiry Date**	**Extended Expiry Date**
65219-445-10	65219-445-01	20 mg/10 mL	G0120621	11/30/2022	05/31/2023
65219-445-10	65219-445-01	20 mg/10 mL	G0150621	11/30/2022	05/31/2023
65219-445-10	65219-445-01	20 mg/10 mL	G0160621	11/30/2022	05/31/2023
65219-445-10	65219-445-01	20 mg/10 mL	G0030921	2/28/2023	08/31/2023
65219-445-10	65219-445-01	20 mg/10 mL	G0040921	2/28/2023	08/31/2023
65219-445-10	65219-445-01	20 mg/10 mL	G0050921	2/28/2023	08/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0200621	11/30/2022	05/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0210621	11/30/2022	05/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0220621	11/30/2022	05/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0060821	1/31/2023	07/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0080821	1/31/2023	07/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0090921	2/28/2023	08/31/2023
65219-447-20	65219-447-02	40 mg/20 mL	G0100921	2/28/2023	08/31/2023

For additional information, please visit the FDA website at,
https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

Adverse Events, Medication Errors, and Product Quality Complaints

Healthcare providers should report adverse reactions, medication errors, or quality problems experienced with the use of Fresenius Kabi's Etomidate product to Fresenius Kabi or the FDA's MedWatch Adverse Event Reporting Program either online, by phone, by regular mail, or by fax:

- Adverse events should be reported to Fresenius Kabi Vigilance at (800) 551-7176, option 5 or adverse.events.usa@fresenius-kabi.com
- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: download form www.fda.gov/MedWatch/getforms.htm or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

Sincerely,

Angie Lindsey
Vice President, Marketing