Fresenius Kabi USA

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November 18, 2020

Subject: Vecuronium Temporary Vial Cap Change Notification. Revision to June 3, 2020 Notification

Dear Healthcare Professional;

The U.S. Food and Drug Administration (FDA) issued regulatory discretion to temporarily manufacture Vecuronium Bromide for Injection with a vial cap (seal) that does not incorporate the usual, "Warning: Paralyzing Agent," statement for 5 months (May 2020 through September 2020). Supply constraints prevented obtaining the components with the usual warning statement on the vial cap. Fresenius Kabi markets the following products.

- Vecuronium Bromide for Injection 10 mg per vial (NDC 63323-781-10)
- Vecuronium Bromide for Injection 10 mg per vial Premier (NDC 63323-781-44)
- Vecuronium Bromide for Injection 20 mg per vial (NDC 63323-782-20)

The vial cap with the required warning statement and the temporary cap without the warning statement are pictured in Figure 1. These products will have the same container and carton labels as before, which includes a paralyzing agent warning statement on the labels; only the vial caps will change. Vecuronium vials with the temporary caps may be distributed from late June 2020 until inventory is exhausted (up to May 31, 2022).

While no additional Vecuronium vials with temporary caps will be produced after September 2020, please be aware that these vials can be in the wholesaler channel and customer inventories up to May 31, 2022. See table below for Lot Information and Expiration Dates.

NDC	Product Description	Product Lot Number	Expiration Date
63323-781-10	Vecuronium Bromide for Injection 10 mg	Lot ZG003	04/2022
63323-781-10	Vecuronium Bromide for Injection 10 mg	Lot ZG004	04/2022
63323-781-44	Vecuronium Bromide for Injection 10 mg Premier	Lot ZG005	04/2022
63323-782-20	Vecuronium Bromide for Injection 20 mg	Lot ZH002	05/2022

Figure 1. Images of current approved cap with warning language (left) and temporary cap (right) for Vecuronium Bromide for Injection 10 mg per vial and 20 mg per vial.

The "paralyzing agent" warning statement assists health care professionals in clearly identifying neuromuscular blocking agents that produce muscle paralysis (including the muscles associated with breathing), and can cause significant patient harm, including death, when used in error.

The absence of the “paralyzing agent” warning statement on the vial cap may cause the vial to look like another medication when stored upright in a cabinet drawer or on a shelf next to each other. Safe handling of these neuromuscular blocking agents is vital to prevent medication errors that could result in serious harm or death. Please ensure this temporary change in vial cap is communicated to all relevant staff and consider implementing additional safety measures (e.g. affixing auxiliary ‘warning: paralyzing agent’ stickers to vial caps) as necessary to minimize potential for medication errors.

Contact Information

Should you have any questions regarding this change, please contact the Fresenius Kabi Medical Department at 1-800-551-7176 or at medinfo.USA@fresenius-kabi.com. Thank you for your attention to this important matter.

Adverse Events, Medication Errors, and Product Quality Complaints

Adverse reactions, medication errors, or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- 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