

Fresenius Kabi USA

June 3, 2020

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www.fresenius-kabi.com/us**Subject:** Vecuronium Temporary Vial Cap Change 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. Supply constraints prevent obtaining the components with the usual warning statement on the vial cap. Fresenius Kabi markets Vecuronium Bromide for Injection 10 mg per vial (NDC 63323-781-10) and 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 will be distributed from late June through September 2020.

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
Fresenius Kabi USA, LLC