

VOLUNTARY MARKET WITHDRAWAL

Adverse Drug Reaction

March 27, 2001

Re: RAPLON® (rapacuronium bromide) for Injection

ALL BATCHES

NDC 0052-0490-15 (100 mg)

NDC 0052-0495-16 (200 mg)

NDC 0052-0490-86 (100 mg sample)

In light of the recent safety issues raised, regarding RAPLON® and its possible association with the occurrence of bronchospasm, we are voluntarily withdrawing the product. We feel a strong responsibility to the clinicians that not only use our products, but also entrust the lives of their patients on the reliability of these products. Our primary concern and goal in this endeavor is to ensure the safety of each patient.

The Food and Drug Administration (FDA) was notified immediately of this decision and the planned market withdrawal of all unused product.

The RAPLON® package insert lists bronchospasm as an adverse event which occurred in 3.2% of patients in premarketing clinical trials. We have now received reports of several serious adverse bronchospasm events including a few unexplained fatalities. In each of these cases the cause is unknown, as there were multiple drugs administered and other conditions present. From our surveillance of postmarketing spontaneous reporting, it appears that the incidence is within labeling, however, the severity of these events, up to and including mortality that has been reported postmarketing, was not seen in clinical trials. These reports are made voluntarily from a population of unknown size and the exact frequency can not be determined.

Please examine your stock immediately to determine if you have any RAPLON® in your inventory. If so, discontinue using the material and have your hospital pharmacy or wholesaler promptly return via parcel post to our West Orange facility: ATTENTION: RETURN MARKET WITHDRAWAL.

You will be reimbursed by credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

Organon is making every effort to fully investigate all reported adverse events and to perform a complete analysis of all clinical and laboratory data available for each report.

We appreciate your assistance in this matter. If there are any questions regarding this market withdrawal please contact:

Customer Services: 8-5 pm
Attention: Sean Gallagher, Assistant Director of Marketing Administration or
Darla Desiderio, Supervisor of Customer Service
Phone: 1-800-241-8812

Sincerely,

Deborah Shapse, MD
Medical Director

Enclosure