

## **URGENT: VOLUNTARY DRUG RECALL**

VERSED<sup>®</sup> Syrup (midazolam HCl) CIV, 118 mL (2mg/mL) bottle, NDC # 0004-0168-51  
Lots U0009-50 and U0010-50, expiration date 04/2003

February 28, 2002

Dear Health Care Professional:

Roche Laboratories is conducting a voluntary drug recall of VERSED<sup>®</sup> Syrup (midazolam HCl) CIV, 118 mL (2mg/mL) bottle, lots U0009-50 and U0010-50, which you may have received on or after December 27, 2001.

VERSED<sup>®</sup> Syrup is indicated for use in pediatric patients for sedation, anxiolysis and amnesia prior to diagnostic, therapeutic or endoscopic procedures or before induction of anesthesia.

Roche is taking this action because of the potential presence of a crystalline precipitate of an insoluble complex of midazolam and saccharin inside the bottle. The presence of this precipitate causes a lack of uniformity in the product and may result in the administration of a super or sub-potent dose. The administration of a variable dose of VERSED<sup>®</sup> Syrup may result in adverse consequences. Due to this possibility we are designating this as a Class I recall. A Class I recall is defined as a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

As a result, you **MUST** take the following action steps:

1. **IMMEDIATELY CEASE ADMINISTRATION** of lots U0009-50 and U0010-50, and remove from active inventory.
2. If you have any units from lots U0009-50 and U0010-50, please immediately contact your supplier, and return your remaining stock to your supplier.
3. Credit for any returned merchandise will be provided through your supplier.

This recall is being made with the knowledge of the Food and Drug Administration.

Please note that this recall does not affect any other package size or strength of VERSED.

We appreciate your assistance with this matter and apologize for any inconvenience. If you have any questions, please feel free to contact Roche at 1-800-526-6367.

Sincerely,

Russell H. Ellison, M.D.  
Vice President, Medical Affairs