

December 29, 2008

## URGENT DRUG RECALL

PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. is notifying all US Direct Accounts, Hospital and Retail Pharmacies of a voluntary recall of the product listed below. **No other product marketed by PriCara®, including other strengths of Ultram ER, is impacted.** This voluntary recall is being conducted in coordination with the U.S. Food and Drug Administration.

<i>Product</i>	<i>NDC Number</i>	<i>Lot Numbers</i>
Ultram®ER (tramadol HCL) Extended Release Tablets 100 mg Manufactured By: Biovail Corporation, Mississauga, ON L5N 8M5, Canada	0062-0653-30	See Attached List

### REASON FOR MARKET ACTION

Extended-release tablets, with lot numbers listed on the attached document, may release the active ingredient at a slightly faster rate than required by the products release rate specification at the 8-hour time point.

### HEALTH ASSESSMENT

A Health Hazard Assessment has been completed and based on the observed rate of release for the extended-release tablets in these lots, there is no expected impact on the safety or efficacy of the product.

### ACTION TO BE TAKEN:

1. Stop dispensing or distributing and quarantine the Ultram®ER 100mg lots on the attached list.
2. Please carry out a physical count of your affected inventory of the indicated Ultram®ER 100mg lots and record this data on the Business Reply Card that is included with this letter and return the reply to Stericycle, Inc. The Business Reply Card is postage paid.
3. **If you DO NOT have the recalled lots**, you must still complete the enclosed Business Reply Card and return it to Stericycle, Inc.
4. **If you DO have product to return**, complete the enclosed packing slip. Place the completed packing slip and product in a shipping carton. Attach the enclosed prepaid UPS Return Service shipping label to the outside of the carton and return to:

**Stericycle, Inc.**  
**Event # 1942**  
**2670 Executive Drive, Suite A**  
**Indianapolis, IN 46241**

### ADDITIONAL INFORMATION

- Credit for returned product will be issued to the direct wholesale and retail chain pharmacy accounts at the current list price. **For assistance with product return, contact Stericycle at 1-888-202-5865.**
- If you have **product related questions**, please contact the Ortho-McNeil Janssen Scientific Affairs Customer Communications Center at 1-800-526-7736.



# PriCara<sup>®</sup>

Division of Ortho-McNeil-Janssen  
Pharmaceuticals, Inc.

Lot List Attachment for the Urgent Drug Recall of Ultram <sup>®</sup> ER (tramadol HCL) Extended Release Tablets 100 mg NDC Code: 0062-0653-30	
Lot	Expiration Date
P07L026	September 2009
P07L027	September 2009
P08A039	September 2009
P08B043	September 2009
P08A040	October 2009
P08A041	October 2009
P08A042	October 2009
P08C040	November 2009
P08E024	November 2009
P08E025	November 2009
P08E026	November 2009
08D010P	January 2010
08D012P	January 2010
P08E055	January 2010
P08E056	January 2010
P08F025	January 2010