

Drug Alert

Important Drug Information



ETHEX Corporation Voluntarily Recalls Specific Lots of 30 mg. and 60 mg. Morphine Sulfate Extended Release Tablets Due to the Potential for Oversized Tablets NDC #58177-320-04 & 58177-330-04 Lot Numbers listed below

FOR IMMEDIATE RELEASE -- St. Louis, MO – June 13, 2008 – ETHEX Corporation announced today that it has voluntarily recalled specific additional lots of morphine sulfate 60 mg extended release tablets, and specific lots of morphine sulfate 30 mg extended release tablets, as a precaution, due to the possible presence of oversized tablets. Oversized tablets may contain as much as two times the labeled level of active morphine sulfate. The recalled lots were distributed by ETHEX Corporation under an “ETHEX” label between June 2006 and May 2008. The lot numbers involved in the recall are:

Morphine Sulfate ER 30mg Tablet/NDC # 58177-320-04: Lots 75090, 77846, 77847, 80048, 83320, 89661, 89665, 90252 through 90258, and 93284

Morphine Sulfate ER 60mg Tablet/NDC # 58177-330-04: Lots 91762 (previously reported), 75091, 75092, 77848 through 77851, 82517, 82518, 83333, 83817, 83862, 84111, 84112, 84315, 84900, 85326, 85335, 85807, 86270 through 86276, 87723, 87939, 88007, 89083, 89668, 89669, 89821, 90260 through 90272, and 91763 through 91765.

No report of unexpected side effects or injury has been received. However, opioids such as morphine, have life-threatening consequences if overdosed. Those consequences can include respiratory depression (difficulty or lack of breathing), and low blood pressure, apnea, and hypotension.

The voluntary recall follows a report that a tablet with as much as double the appropriate thickness was identified in a previously recalled lot. No oversized tablets have been identified in any additional distributed lot of these products and, based on our investigation, there are likely to be few, if any, oversized tablets in the recalled lots. The decision to recall the additional lots listed above has been taken as a responsible precaution because of the possibility that there may be oversized tablets in those lots.

The 60 mg product is a white oval tablet with “60” on one side, and “E” on the reverse. The 30 mg product is a pink oval tablet with “30” on one side, and “E” on the reverse.

Any customer inquiries related to this action should be addressed to ETHEX Customer Service at 1-800-321-1705, or fax to ETHEX Customer Service at 314-646-3751 or sent via email to: customer-service@ethex.com with representatives available Monday through Friday, 8 am to 5 pm CDT.

ETHEX Corporation has initiated recall notifications to wholesalers and retailers who have received any inventory of the recalled lots of this product with instructions for returning the recalled product and, if they have not already done so, they are urged to contact the number above regarding procedures for returning the recalled product. If consumers have any questions about the recall, they should call the number above, their physician, their pharmacist or other health care provider.

This recall is being conducted with the knowledge of the Food and Drug Administration (FDA).

Any adverse reactions experienced with the use of this product, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

8300 E. Maplewood Ave | Suite 100 | Greenwood Village, CO 80111 | 1.800.950.9120