



January 28, 2009

## Medication Recall Alert

**MEDICATIONS:** Multiple Medications, Ethex Corp. and Ther-Rx Corp., both subsidiaries of KV Pharmaceutical

**NDC NUMBERS:** See Below

**LOT NUMBERS:** All Lots

**ISSUE:** A Voluntary Recall of several medications manufactured by Ethex Corporation and Ther-Rx Corporation (both subsidiaries of KV Pharmaceutical). This recall is a precautionary measure because they may have been manufactured under conditions that did not comply with current Good Manufacturing Practices (cGMPs).

The following was posted on the FDA Med Watch Web site on January 28, 2009:

“ETHEX Corporation, a subsidiary of KV Pharmaceutical (NYSE: KVa/KVb), is issuing, as previously disclosed by KV Pharmaceutical Company on January 26, 2009, a nationwide voluntary recall of the products identified below (all lots within their expiration dates) at a wholesale or a retail level as a precautionary measure because they may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practices (cGMPs). Some of these products have had specific lots recalled earlier due to defects found, including oversized tablets delivering higher than labeled doses. These additional products are being removed to assure that no other defective products remain in the marketplace.

**Patients who may have these medicines in their possession should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medication may place patients at risk. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products, or to obtain replacement medications or prescriptions.**

### Products Recalled to WHOLESale Level:

Amlodipine Besylate Tablets, 10mg (58177-538-26 & 538-11)  
Amlodipine Besylate Tablets, 2.5mg (58177-536-26)  
Amlodipine Besylate Tablets, 5mg (58177-537-26, 537-07 & 537-11)  
Benazepril HCl Tablets, 10mg (58177-342-04 & 342-08)  
Benazepril HCl Tablets, 20mg (58177-343-04 & 343-08)  
Benazepril HCl Tablets, 40mg, (58177-344-04 & 344-08)  
Benazepril HCl Tablets, 5mg (58177-341-04)  
Benzonatate Capsules, 100mg (58177-091-04 & 091-08)  
Benzonatate Capsules, 200mg (58177-092-04 & 092-08)  
Bromfenex ER Capsules (58177-019-04)  
Bromfenex PD ER Capsules (58177-020-04)  
Buspirone HCl Tablets, 10mg (58177-265-04 & 265-08)  
Buspirone HCl Tablets, 15mg (58177-309-04 & 309-08)  
Buspirone HCl Tablets, 5mg (58177-264-04 & 264-08)

Codeine Phosphate/Guaifenesin Tablets, 10mg (58177-223-04)  
Dextroamphetamine Sulfate Tablets, 10mg (58177-312-04)  
Dextroamphetamine Sulfate Tablets, 5mg (58177-311-04)  
Dextroamphetamine Tablets, 10mg (58177-312-04)  
Diltiazem HC1 Capsules, 120mg (58177-061-11)  
Diltiazem HC1 Capsules, 120mg (58177-061-19 & 061-26)  
Diltiazem HC1 Capsules, 180mg (58177-062-09 & 062-11)  
Diltiazem HC1 Capsules, 180mg (58177-062-19 & 062-26)  
Diltiazem HC1 Capsules, 240mg (58177-063-09 & 063-11)  
Diltiazem HC1 Capsules, 240mg (58177-063-19 & 063-26)  
Diltiazem HC1 Capsules, 300mg (58177-064-19 & 064-26)  
Diltiazem HC1 Capsules, 360mg (58177-065-09 & 065-11)  
Diltiazem HC1 Capsules, 360mg (58177-065-19 & 065-26)  
Diltiazem HC1 Capsules, 420mg (58177-066-09 & 066-11)  
Diltiazem HC1 Capsules, 420mg (58177-066-19 & 066-26)  
Disopyramide Phosphate ER Capsules, 150mg (58177-002-04)  
Doxazosin Mesylate Tablets, 1mg (58177-266-04 & 266-08)  
Doxazosin Mesylate Tablets, 2mg (58177-267-04 & 267-08)  
Doxazosin Mesylate Tablets, 4mg (58177-268-04 & 268-08)  
Doxazosin Mesylate Tablets, 8mg (58177-269-04 & 269-08)  
Ethedent Chewable Tablets, .25mg (58177-432-40)  
Ethedent Chewable Tablets, .5mg (58177-433-40 & 433-09)  
Ethedent Chewable Tablets, 1mg (58177-434-40 & 434-09)  
EthexDerm BPW-10, 10% (58177-929-65)  
EthexDerm BPW-5, 5% (58177-928-65)  
Ethezyme 650 (58177-868-02)  
Ethezyme 830 Papain-Urea (58177-816-02)  
Ethezyme Papain-Urea (58177-804-02)  
ETH-Oxydose Concentrated Solution (58177-914-04 & 914-56)  
Guaifenex DM ER Tablets (58177-213-04)  
Guaifenex GP ER Tablets (58177-373-04)  
Guaifenex PSE 120 ER Tablets (58177-208-04)  
Guaifenex PSE 60 ER Tablets (58177-214-04)  
Guaifenex PSE 80 Tablets (58177-413-04)  
Guaifenex PSE 85 Tablets (58177-478-04)  
Hista-Vent DA Tablets (58177-227-04)  
Hista-Vent PSE tablets (58177-426-04)  
Histinex HC Liquid (58177-877-07 & 877-12)  
Histinex PV Liquid (58177-883-07)  
Hydrocodone Bitartrate & Acetaminophen Liquid (58177-909-07)  
Hydrocodone Bitartrate/Guaifenesin Liquid (58177-881-07)  
Hydrocortisone and Iodoquinol Cream, 1% (58177-803-02)  
Hydroquinone 4% Cream w/SS, 1oz. (58177-802-02)  
Hydroquinone 4% Cream, 1oz. (58177-801-02)  
Hydro-Tussin CBX Liquid (58177-924-07)  
Hydro-Tussin DHC Syrup (58177-926-07)  
Hydro-Tussin DM Liquid (58177-906-07)  
Hydro-Tussin EXP Liquid (58177-927-07)  
HydroTussin HC Syrup (58177-915-07)  
Hydro-Tussin Liquid (58177-890-07)  
Hydro-Tussin XP Liquid (58177-916-07)  
Hyoscyamine Orally Disintegrating Tablets, .125mg (58177-423-04)  
Hyoscyamine Sublingual Tablets, .125mg (58177-255-04)  
Hyoscyamine Sulfate ER Tablets, .375mg (58177-237-04)  
Hyoscyamine Sulfate ER Capsules, .375mg (58177-017-04)  
Hyoscyamine Sulfate Oral Tablets, .125mg (58177-274-04)  
Isosorbide Mononitrate ER Tablets, 120mg (58177-201-04)

Isosorbide Mononitrate ER Tablets, 30mg (58177-222-04, 222-08 & 222-11)  
Isosorbide Mononitrate ER Tablets, 60mg (58177-238-04, 238-08 & 238-11)

Meperidine/Promethazine Capsules (58177-027-04)  
Morphine InveAmp, 20mg x 1mL (58177-886-56)  
Morphine InveAmp, 5mg/.25mL (58177-888-80)  
Morphine Sulfate Concentrated Oral Solution 20mg/1ml (58177-886-01, 886-03 & 886-05)  
Morphine Sulfate Concentrated Oral Solution, 20mg/1ml (58177-886-57)  
Morphine Sulfate ER Tablets, 100mg (58177-340-04)  
Morphine Sulfate ER Tablets, 15mg (58177-310-04)  
Morphine Sulfate ER Tablets, 200mg (58177-380-04)  
Morphine Sulfate ER Tablets, 30mg (58177-320-04)  
Morphine Sulfate ER Tablets, 60mg (58177-330-04)  
Morphine Sulfate IR Tablets, 15mg (58177-313-04)  
Morphine Sulfate IR Tablets, 30mg (58177-314-04)  
NitroQuick Sublingual Tablets, .3mg (58177-323-04)  
NitroQuick Sublingual Tablets, .4mg (58177-324-18 & 324-04)  
NitroQuick Sublingual Tablets, .6mg (58177-325-04)  
Nystatin Topical Powder, USP 15 grams (58177-839-45)  
Nystatin Topical Powder, USP 30 grams (58177-839-46)  
Nystatin Topical Powder, USP 60 grams (58177-839-61)  
Ondansetron Orally Disintegrating Tablets, 4mg (58177-363-22)  
Ondansetron Orally Disintegrating Tablets, 8mg (58177-364-22 & 364-56)  
Oxycodone HCl Capsules, 5mg (58177-041-04 & 041-11)  
Oxycodone HCl IR Tablets, 10mg (58177-461-04)  
Oxycodone HCl IR Tablets, 15mg, (58177-445-04)  
Oxycodone HCl IR Tablets, 20mg (58177-462-04)  
Oxycodone HCl IR Tablets, 30mg (58177-446-04)  
Oxycodone HCl IR Tablets, 5mg (58177-625-04 & 625-11)  
Pangestyme CN 20 (58177-030-04)  
Pangestyme CN10 (58177-029-04)  
Pangestyme EC 100 (58177-031-04)  
Pangestyme EC 250 (58177-031-06)  
Pangestyme MT16 (58177-028-04)  
Pangestyme UL12 (58177-048-04)  
Pangestyme UL18 (58177-049-04)  
Pangestyme UL20 (58177-050-04)  
PhenaVent Capsules (58177-078-19)  
PhenaVent D Tablets (58177-444-04)  
PhenaVent LA Capsules (58177-095-19)  
PhenaVent PED Capsules (58177-079-04)  
Plavix 800 (58177-416-04 & 416-08)  
Potassium Chloride ER Capsules, 10mEq (58177-001-04, 001-08, 001-09, & 001-11)  
Potassium Chloride ER Capsules, 8mEq (58177-677-04 & 677-08)  
Potassium Chloride ER Tablets, 20mEq (58177-202-04, 202-08, 202-09 & 202-11)  
Prednisolone Sodium Oral Solution (58177-932-05)  
Prednisolone Syrup 15mg/5mL (58177-910-05 & 910-07)  
Prednisolone Syrup 5mg/5mL (58177-912-03)  
Propafenone HCl Tablets, 150mg (58177-331-04 & 331-11)  
Propafenone HCl Tablets, 225mg (58177-332-04)  
Propafenone HCl Tablets, 300mg (58177-333-04)  
Pseudovent 400 Capsules (58177-096-04)  
Pseudovent Capsules (58177-045-04)  
Pseudovent PED Capsules (58177-046-04)  
Tri-Vent DM Syrup (58177-925-07)  
Tri-Vent DPC Liquid (58177-923-07)  
Tri-Vent HC Liquid (58177-920-07)

**Products Recalled to RETAIL PHARMACY Level:**

Hydromorphone HCl Tablets, 2mg (58177-620-04 & 620-11)  
Hydromorphone HCl Tablets, 4mg (58177-621-04 & 621-11)  
Hydromorphone HCl Tablets, 8mg (58177-449-04)

Metoprolol Succinate ER Tablets, 50mg (58177-369-04, 369-09 & 369-11)  
Metoprolol Succinate ER Tablets, 100mg (58177-368-04, 368-09 & 368-11)  
Metoprolol Succinate ER Tablets, 25mg (58177-293-04, 293-09 & 293-11)  
Metoprolol Succinate ER Tablets, 200mg (58177-358-04, 358-09 & 358-11)

**Any wholesale or retail customer inquiries related to this action should be addressed to ETHEX Customer Service at 1-800-748-1472, faxed to ETHEX Customer Service at 314-646-3788, or e-mailed to [customer-service@ethex.com](mailto:customer-service@ethex.com). Representatives are available Monday through Friday, 8 am to 5 pm CST.**

ETHEX Corporation has initiated recall notifications to wholesalers (and to retailers for Hydromorphone HCl and Metoprolol Succinate only) nationwide who received any inventory of the recalled products with instructions for returning the recalled products. Patients with questions about the recall should call the telephone number above, or contact their healthcare providers.”

**The following was also posted on the FDA Med Watch Web site on January 28, 2009:**

“Ther-Rx Corporation, a subsidiary of KV Pharmaceutical (NYSE: KVa/KVb), is issuing, as previously disclosed by KV Pharmaceutical Company on January 26, 2009, a voluntary nationwide recall of the products identified below (all lots within expiration) as a precautionary measure because they may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practices (cGMPs).

**Patients who may have these medicines in their possession should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medication may place patients at risk. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products, or to obtain replacement medications or prescriptions.**

**Products Recalled to WHOLESale Level:**

Gynazole-1®, NDC 64011-0001-08  
Clindesse®, NDC 64011-0124-08  
microK® Extencaps® 8mEq 100, NDC 64011-0010-04  
microK® Extencaps® 8mEq UD, NDC 64011-0010-11  
microK® Extencaps® 8mEq 500, NDC 64011-0010-08  
microK® Extencaps® 10mEq 100, NDC 64011-0009-04  
microK® Extencaps® 10mEq UD, NDC 64011-0009-11  
microK® Extencaps® 10mEq 500, NDC 64011-0009-08

**Any customer inquiries related to this action should be addressed to Ther-Rx Customer Service at (877) 567-7676, or faxed to Ther-Rx Customer Service at (314) 646-3701, or e-mailed to [info@ther-rx.com](mailto:info@ther-rx.com). Representatives are available Monday through Friday, 8 am to 5 pm CST.**

Ther-Rx Corporation has initiated recall notifications to wholesalers nationwide who received any inventory of the recalled products with instructions for returning the recalled products. Patients with questions about the recall should call the telephone number above, or contact their health care providers.”

These recalls are being conducted with the knowledge of the U.S. Food and Drug Administration (FDA). At this time, the companies are unable to determine when distribution of these products will resume.

**Complete copies of the accompanying “Recall—Firm Press Releases” dated January 28, 2009 from the FDA may be viewed at:**

[http://www.fda.gov/oc/po/firmrecalls/ethex01\\_09.html](http://www.fda.gov/oc/po/firmrecalls/ethex01_09.html)

[http://www.fda.gov/oc/po/firmrecalls/therrx01\\_09.html](http://www.fda.gov/oc/po/firmrecalls/therrx01_09.html)