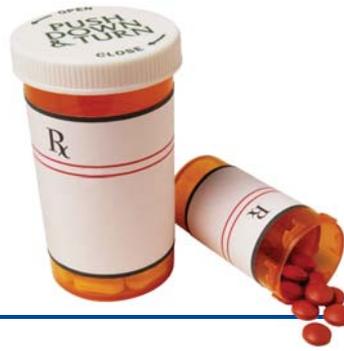


# Rx

January  
2009

# UPDATE



## KV Pharmaceutical Recalls Most Products from ETHEX and Ther-Rx Subsidiaries

On January, 28, 2009, KV Pharmaceutical issued a nationwide recall of more than 80 medications distributed by subsidiaries ETHEX Corporation and Ther-Rx Corporation.

This recall was issued as a precautionary measure because affected products may have been manufactured under conditions that did not sufficiently comply with the U.S. Food and Drug Administration's (FDA) current standards for Good Manufacturing Practices (GMPs). GMPs are regulations set forth by the FDA that define the minimum current practices to be used for manufacturing, processing, and packing or holding of a drug to ensure that the drug meets expected safety, identity, strength, quality and purity standards. Specific lots of several medications included in this action have previously been recalled due to manufacturing defects, 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.

This recall has been classified by the FDA as a Class III recall. A Class III recall means that patient exposure to affected products is not likely to cause adverse health consequences. This precautionary action is focused on removing products from the wholesale and pharmacy levels and does not extend to the patient level. This recall **only** affects products manufactured by KV Pharmaceutical and distributed under an ETHEX or Ther-Rx label. It **does not** affect any other generic medications manufactured and distributed by other companies.

Patients with questions about medications affected by this recall may contact their pharmacy. If they are in possession of a recalled product, they should continue to take the medication in accordance with their physician's instructions, as suddenly stopping needed medication may place them at risk. Patients should contact their physician or health care provider if they experience any problems possibly related to taking or using these products, or to obtain replacement medications or prescriptions.

Inquiries related to this recall should be addressed to ETHEX Customer Service at 1-800-748-1472 or Ther-Rx Customer Service at 1-877-567-7676. Representatives are available Monday through Friday, 8 a.m. to 5 p.m. CST.

If you have any questions regarding this topic, please call the Catalyst Rx Clinical Department at 702-869-4600.

### Sources:

<http://www.ethex.com/news/pressRelease012809.aspx>

<http://www.ther-rx.com/pressRelease012809.aspx>

## KV Pharmaceutical Recalls Most Products from ETHEX and Ther-Rx Subsidiaries (cont.)

This Class III recall includes all lots within expiration date of the products listed below.

### ETHEX Corporation Recalled Products

Amlodipine besylate tablets 2.5mg, 5mg, 10mg  
Benazepril HCl tablets 5mg, 10mg, 20mg, 40mg  
Benzonatate capsules 100mg, 200mg  
Bromfenex ER capsules 100mg  
Bromfenex PD ER capsules  
Buspirone HCl tablets 5mg, 10mg, 15mg  
Codeine phosphate/guaifenesin tablets 10mg  
Dextroamphetamine tablets 10mg  
Dextroamphetamine sulfate tablets 5, 10mg  
Diltiazem HCl capsules 120mg, 180mg, 240mg, 300mg, 360mg, 420mg  
Disopyramide phosphate ER capsules 150mg  
Doxazosin mesylate tablets 1mg, 2mg, 4mg, 8mg  
Ethedent chewable tablets 0.25mg, 0.5mg, 1mg  
EthexDerm BPW-5, 5%, BPW-10, 10%  
Ethezyme 650, 830 papain-urea ointment  
Ethezyme papain-urea ointment  
ETH-Oxydose concentrated solution  
Guaifenex DM ER tablets  
Guaifenex GP ER tablets  
Guaifenex PSE ER tablets 60, 120  
Guaifenex PSE tablets 80, 85  
Hista-Vent DA tablets  
Hista-Vent PSE tablets  
Histinex HC liquid  
Histinex PV liquid  
Hydrocodone bitartrate & acetaminophen liquid  
Hydrocodone bitartrate/guaifenesin liquid  
Hydrocortisone and iodoquinol cream 1%  
Hydromorphone HCl tablets 2mg, 4mg, 8mg  
Hydroquinone 4% cream 1oz  
Hydroquinone 4% cream w/SS 1oz  
Hydro-Tussin CBX liquid  
Hydro-Tussin DHC syrup  
Hydro-Tussin DM liquid  
Hydro-Tussin EXP liquid  
Hydro-Tussin HC syrup  
Hydro-Tussin liquid  
Hydro-Tussin XP liquid  
Hyoscyamine orally disintegrating tablets 0.125mg  
Hyoscyamine sublingual tablets 0.125mg  
Hyoscyamine sulfate ER capsules and ER tablets 0.375mg  
Hyoscyamine sulfate oral tablets 0.125mg  
Isosorbide mononitrate ER tablets 30mg, 60mg, 120mg  
Meperidine/promethazine capsules  
Metoprolol succinate ER tablets 25mg, 50mg, 100mg, 200mg  
Morphine InveAmp 5mg/0.25mL and 20mg/1mL  
Morphine sulfate concentrated oral solution 20mg/1mL  
Morphine sulfate ER tablets 15mg, 30mg, 60mg, 100mg, 200mg  
Morphine sulfate IR tablets 15mg, 30mg  
NitroQuick sublingual tablets 0.3mg, 0.4mg, 0.6mg  
Nystatin topical powder USP 15g, 30g, 60g  
Ondansetron orally disintegrating tablets 4mg, 8mg  
Oxycodone HCl capsules 5mg  
Oxycodone HCl IR tablets 5mg, 10mg, 15mg, 20mg, 30mg  
Pangestyme CN 10, 20  
Pangestyme EC100, 250  
Pangestyme MT16  
Pangestyme UL 12, 18, 20  
PhenaVent capsules  
PhenaVent D tablets  
PhenaVent LA capsules  
PhenaVent PED capsules  
Plaretase 800  
Potassium chloride ER capsules 8meq and 10meq,  
Potassium chloride ER tablets 20meq  
Prednisolone sodium oral solution  
Prednisolone syrup 5mg/5mL and 15mg/5mL  
Propafenone HCl tablets 150mg, 225mg, 300mg  
Pseudovent capsules  
Pseudovent 400 capsules  
Pseudovent PED capsules  
Tri-Vent DM syrup  
Tri-Vent DPC liquid  
Tri-Vent HC liquid

### Ther-Rx Recalled Products

Clindesse  
Gynazole-1  
microK Extencaps 8meq  
microK Extencaps 10meq