
To: All IEHP PCPs, All IEHP Pharmacy Providers
From: IEHP Pharmaceutical Services
Date: 1 September 2023
Subject: **URGENT: Recalls, Market Withdrawals & Safety Alerts, August 2023**

Dear IEHP Providers,

According to the FDA recall guidance, Title 21 Code of Federal Regulations Part 7 (21 CFR part 7), recalled products must be promptly removed or corrected. In an effort to promote health and wellness of our members, please review your records and notify members who may have been impacted by these recalls and market withdrawals.

Included in this correspondence are the Class I and Class II products that have been recalled during this timeframe.

The Recalls, Market Withdrawals & Safety Alerts notifications are available on our website under IEHP Safety Resources: <https://www.iehp.org/en/providers/pharmacy-services/safety-resources>

Additional information can be found at:

1. FDA Recalls, Market Withdrawals, & Safety Alerts:
<https://www.fda.gov/Safety/Recalls/default.htm>
2. FDA Enforcement Report:
<http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>
3. IEHP Plan Updates (Correspondence):
<https://www.iehp.org/en/providers/plan-updates>
4. IEHP Pharmacy Times Notices:
<https://www.iehp.org/en/providers/pharmacy-services/provider-communications---pharmacy>

If you have any questions or comments regarding this recall, please email IEHP Clinical Pharmacy Program team at ClinicalPharmacyPrograms@iehp.org .

Sincerely,
IEHP Pharmaceutical Services

Product Name	Classification
Tydemy (drospirenone, ethinyl estradiol and levomefolate calcium tablets, 3 mg/0.03 mg/0.451 mg and levomefolate calcium tablets 0.451 mg)	Class I
activator concentrate, Sodium Fluoride 0.96% in Activator Concentrate; 0.08% in diluted Activator Solution	Class II
ALCOLADO RELAMPAGO (Menthol and Camphor), 1% and 1.5%	Class II
All Over-The-Counter (OTC) drug products warehoused, salvaged, and sold by Inmar	Class II
AstrinGyn (Ferric Subsulfate) Aqueous, 259 mg/g, 8 gm Single Use Vials	Class II
Blis-To-Sol Liquid (Tolnaftate), 1%	Class II
Cardioplegia Solution 100 mEq K, Induction 8:1 High Potassium / Low dextrose IV Bag	Class II
Cardioplegia Solution 106 mEq K Modified St. Thomas Solution High Potassium High Sodium Bicarbonate IV Bag	Class II
Cardioplegia Solution 108 mEq K Induction 8:1 High Potassium IV Bag	Class II
Cardioplegia Solution 12 mEq K Maintenance 4:1 in Ringer's Low Potassium IV Bag	Class II
Cardioplegia Solution 122 mEq K Modified St. Thomas Formula High Potassium IV Bag	Class II
Cardioplegia Solution 15 mEq K Reperfusate 4:1 low potassium IV Bag	Class II
Cardioplegia Solution 15 mEq K, Reperfusate 4:1 low potassium/low tromethamine	Class II
Cardioplegia Solution 20 mEq K Maintenance 4:1 Low Potassium IV Bag	Class II
Cardioplegia Solution 24 mEq K Maintenance 8:1 Low Potassium IV Bag	Class II
Cardioplegia Solution 24 mEq K Maintenance 8:1 non-enriched Low Potassium IV Bag	Class II
Cardioplegia Solution 25 mEq K Sutter Cardioplegia IV Bag	Class II
Cardioplegia Solution 30 mEq K Induction 4:1 High Potassium IV Bag	Class II
Cardioplegia Solution 36 mEq K Induction 4:1 High Potassium/Low tromethamine IV Bag	Class II
Cardioplegia Solution 36 mEq K Maintenance 8:1 low Potassium / low dextrose IV Bag	Class II
Cardioplegia Solution 40 mEq K Warm Induction 4:1 High Potassium IV Bag	Class II
Cardioplegia Solution 48 mEq K Induction 4:1 in Ringer's High Potassium IV Bag	Class II
Cardioplegia Solution 60 mEq K Induction 4:1 High Potassium IV Bag	Class II
Cardioplegia Solution 7.5 mEq K Reperfusate 4:1 low potassium IV Bag	Class II
Cardioplegia Solution 70 mEq K Induction 8:1 non-enriched High Potassium IV Bag	Class II
Cardioplegia Solution 70 mEq K Modified St. Thomas Formula low potassium IV Bag	Class II
Cardioplegia Solution del Nido Formula IV Bag Total Volume = 1,052.8 mL FOR INTRACARDIAC PERFUSION USE ONLY PLASMA-LYTE A 1000 mL Mannitol 20% 16.3 mL, Sodium Bicarbonate 8.4% 13 mL Potassium Chloride 2 mEq/mL 13 mL Magnesium Sulfate 4.06 mEq/mL 4 mL Lidocaine 2% 6.5 mL Approx.Osmolarity 386 mOsm/L	Class II
Cardioplegia Solution HIGH K Induction 4:1 Plasmalyte, High Potassium IV Bag	Class II
Cardioplegia Solution HIGH K Induction 4:1 Plasmalyte/Tromethamine High Potassium IV Bags	Class II
Cardioplegia Solution IV Bag Crystalliod Induction	Class II
Cardioplegia Solution Leesburg Cardioplegia IV Bag	Class II

Cardioplegia Solution low K Maintenance 4:1 Plasmalyte Low Potassium IV Bag	Class II
Cardioplegia Solution low K Maintenance 4:1 Plasmalyte/Tromethamine Low Potassium IV Bag	Class II
Cromolyn Sodium Oral Solution (Concentrate) 100 mg/5 mL 96 Plastic Ampules per carton	Class II
Diclofenac Sodium Topical Solution 2% w/w	Class II
dilTIAZem 125mg/125mL (1 mg/mL) added to 0.9% sodium chloride IV Bag	Class II
dilTIAZem 125mg/125mL (1 mg/mL) added to dextrose 5% IV Bag	Class II
EPINEPHrine 2 mg added to dextrose 5% 250mL Concentration = 8 mcg/mL IV Bag	Class II
EPINEPHrine 4mg/250mL added to 0.9% sodium chloride IV Bag	Class II
EPINEPHrine 8mg/250ml added to dextrose 5% 32 mcg/mL IV Bag	Class II
EPINEPHrine added to dextrose 5% 4mg/250ml IV Bag	Class II
FentaNYL 500 mcg/250 mL - Bupivacaine HCl 0.1% in 0.9% Sodium Chloride 250mL Bag Injection for Epidural Use (fentaNYL Concentration - 2 mcg/mL)	Class II
Glycopyrrolate 1 mg/5 mL (0.2 mg/mL) For Anesthesia Use Syringe	Class II
Helix CBD Clinical Cream (Menthol 7.4%)	Class II
Helix CBD Therapy Cream (Menthol 7.4%)	Class II
Helix Pain Relieving Cream (Menthol 7.4%)	Class II
Helix Tri-Active Therapy Cream (Camphor 3.2%, Menthol 7.4%, Methyl salicylate 12.5%)	Class II
hello wild strawberry fluoride toothpaste, sodium fluoride 0.24% (0.15% w/v fluoride ion), NET WT 4.2 OZ (119 g)	Class II
Heparin 2500 units added to 0.9% sodium chloride 250mL CONCENTRATION = 10 units/mL IV Bag	Class II
Heparin 2500 units/500mL added to 0.9% sodium chloride 5 units/mL IV Bag	Class II
Heparin 4000 units/1000mL added to 0.9% sodium chloride 4 units/mL IV Bag	Class II
Heparin 5000 units/500mL added to 0.9% sodium chloride 10 units/mL IV Bag	Class II
Heparin 7500 units added to 0.9% sodium chloride 1000mL CONCENTRATION = 7.5 units/mL IV Bag	Class II
Lugol's (Strong Iodine Solution USP), Each mL contains Iodine 0.05gm and potassium iodide 0.100gm	Class II
Methylphenidate Hydrochloride 20mg Tablets	Class II
NAD+ 200mg/ml, 10ml vials	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 6%/Dextrose 10% with Calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 2%/Dextrose 10% with **low calcium** and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 2%/Dextrose 10% with Calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 2%/Dextrose 10% with CALCIV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (Trophamine) 2%/Dextrose 5% with Calcium and Heparin IV Bag	Class II

Neonatal TPN Starter Bag Amino Acids (trophamine) 2.5%/Dextrose 10% IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (Trophamine) 2.5%/Dextrose 10% with Calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (Trophamine) 3%/Dextrose 10% IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3%/Dextrose 10% with **low calcium** and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3%/Dextrose 10% with Calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3%/Dextrose 10% with Calcium IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3%/Dextrose 5% with **low calcium** and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3%/Dextrose 5% with Calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3%/Dextrose 5% with Calcium IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3.5%/Dextrose 10% IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3.5%/Dextrose 10% with **low calcium** and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (Trophamine) 3.5%/Dextrose 10% with Calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3.5%/Dextrose 10% with Calcium IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 3.5%/Dextrose 10% with Heparin IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 4%/Dextrose 10% IV Bag	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 4%/Dextrose 10% with CALCIUM Calcium and Heparin IV Bags	Class II
Neonatal TPN Starter Bag Amino Acids (trophamine) 6%/Dextrose 10% with low calcium and Heparin IV Bag	Class II
Neonatal TPN Starter Bag, Amino Acids (trophamine) 2%/Dextrose 10% IV Bag	Class II
Neostigmine 5 mg/5mL (1mg/mL) Syringe	Class II
Norepinephrine 16 mg added to dextrose 5% 250 mL IV Bag CONCENTRATION 64 mcg/mL	Class II
NORepinephrine 4 mg/250 mL added to 0.9% sodium chloride 16 mcg/mL IV Bag	Class II
Oxacillin for Injection 1 gram per vial for IV or IM Use	Class II
Oxacillin for Injection 10 gram per pharmacy Bulk Package bottle for Intravenous Use	Class II
Oxacillin for Injection 2 grams per vial for IV or IM Use	Class II
oxyTOCIN 10 units added to Lactated Ringer's 500 mL IV Bag	Class II
oxyTOCIN 15 units added to 0.9% sodium chloride 250 mL IV Bag	Class II
oxyTOCIN 15 units added to Lactated Ringer's 250 mL IV Bag	Class II
oxyTOCIN 20 units added to 0.9% sodium chloride 1,000 mL IV Bag	Class II
oxyTOCIN 20 units added to dextrose 5%/lactated ringers IV Bag	Class II
oxyTOCIN 20 units added to Lactated Ringer's IV Bag	Class II

oxyTOCIN 30 units added to 0.9% sodium chloride 500 mL IV Bag	Class II
oxyTOCIN 30 units added to dextrose 5%/lactated ringers 500 mL IV Bag	Class II
oxyTOCIN 30 units added to Lactated Ringer's 500 mL IV Bag	Class II
oxyTOCIN 40 units added to 0.9% sodium chloride 1000 mL IV Bag	Class II
PHENYLEphrine 1,000 mcg/10mL, (100mcg/mL) in 0.9% sodium chloride Syringe	Class II
PHENYLEphrine 20mg/250ml added to 0.9% sodium chloride IV Bag	Class II
phenylephrine 25mg added to 0.9% sodium chloride 250 mL IV Bag	Class II
PHENYLEphrine 40mg/250ml added to 0.9% sodium chloride IV Bag	Class II
phenylephrine 50 mg added to 0.9% sodium chloride 250mL CONCENTRATION = 200mcg/mL IV Bag	Class II
PHENYLEphrine, 10mg/250ml added to 0.9% sodium chloride 40mcg/mL IV Bag	Class II
Potassium phosphate 15 mmole added to 0.9% sodium Chloride 250 mL IV Bag	Class II
Potassium Phosphate 30 mmole added to 0.9% sodium Chloride 500mL IV Bag	Class II
Protex Foaming Hand Sanitizer (Benzalkonium Chloride 0.13%)	Class II
Rocuronium 50 mg/5 mL (10 mg/mL) Syringes	Class II
Rufinamide Tablets, USP 200 mg	Class II
Rufinamide Tablets, USP 400 mg	Class II
Safe Tussin DM Cough + Chest Congestion (Dextromethorphan HBr/ Cough Suppressant Guaifenesin/Expectorant)	Class II
Safe Tussin PM Night Time Cough Relief (Cough Suppressant/Antihistamine)	Class II
Semaglutide/Cyanocobalamin 2mg/0.4mg/mL, 1mLvials	Class II
Succinylcholine 200 mg/10 mL (20 mg/mL) Syringe	Class II
Testosterone Cypionate-Testosterone Propionate 180-20 mg/mL in cottonseed oil Compounded Rx for Intramuscular Use Only	Class II
Transplant Solution Plasma-Lyte A - 75 ml MSA/MSG 0.92 Molar -60 ml dextrose 70% 21.3 ml IV Bag	Class II
Unguentine Ointment, (Camphor 3.0%, Phenol 2.5%, Tannic Acid 2.2%, Zinc Oxide 6.6%)	Class II
Vancomycin 1 g/250 mL added to 0.9% sodium chloride 4 mg/mL IV Bag	Class II
Vancomycin 1.25 g/250 mL added to 0.9% Sodium Chloride 5 mg/mL IV Bag	Class II
Vancomycin 1.25 g/250 mL added to dextrose 5%, 5 mg/mL IV Bag	Class II
Vancomycin 1.5 g/250 mL added to 0.9% sodium chloride, 6 mg/mL IV Bag	Class II
Vancomycin 1.5 g/250mL added to 5% dextrose 6 mg/mL IV Bag	Class II
Vancomycin 1.5 g/500 mL added to 0.9% sodium chloride 3 mg/mL IV Bag	Class II
Vancomycin 1.75g added to 0.9% sodium chloride 500mL IV Bag	Class II
Vancomycin 2 g/500 mL added to 0.9% Sodium Chloride 4 mg/mL IV Bag	Class II
Vancomycin 750 mg/250 mL added to 0.9% Sodium Chloride (3 mg/mL) IV Bag	Class II
YAGER'S LINIMENT (Camphor and Turpentine Oil) 3.1% and 8.12%	Class II

Class I = Class I Recall, **Class II** = Class II Recall, **MW** = Market Withdrawal