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Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

September 08, 2022

URGENT: Recalls, Market Withdrawals, & Safety Alerts

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.

Product Name	Product Code	Lot # and Exp. Date	Classification	Recalling Firm
Nifedipine WSP 0.2% Ointment, 60 gram tubes (Compound)	NDC Not Provided	06162022@30, BUD 12/13/2022	Class I	Valor Compounding Pharmacy, Inc DBA Valor Compounding Pharmacy
Insulin Glargine (Insulin glargine-yfgn) 100 units/mL (U-100) Injection	NDC: 49502-0394-71; 49502-0394-75	BF21002895 Exp. 082023	Class I	Mylan Pharmaceuticals Inc
Propofol Injectable Emulsion, 1 g/100 mL (10 mg/mL)	NDC: 00409-4699-54; 00409-4699-24	DX9067 Exp. 05/1/2023	Class I	Pfizer Inc.
Divalproex Sodium 500 mg Delayed-Release Tablets	NDC: 62756-0798-88	HAC1312A Exp. 05/2024	Class II	SUN PHARMACEUTICAL INDUSTRIES INC
Testosterone Gel 1% (25mg testosterone/2.5g of gel) 2.5 g per unit dose	NDC: 00591-3216-17; 00591-3216-30	1403180 Exp. 10/2022	Class II	Teva Pharmaceuticals USA Inc
Lansoprazole 15 mg Delayed-Release Orally Disintegrating Tablets	NDC: 43598-0560-78	T2100514 Exp. 01/2023	Class II	Dr. Reddy's Laboratories, Inc.
Lansoprazole 30 mg Delayed-Release Orally Disintegrating Tablets	NDC: 43598-0561-78	T2100515 Exp. 01/2023	Class II	Dr. Reddy's Laboratories, Inc.
Irbesartan 150 mg Tablets	NDC: 59746-0448-90	IB220023A Exp. 08/2022	Class II	Jubilant Cadista Pharmaceuticals, Inc.



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Irbesartan 75 mg Tablets	NDC: 59746-0447-90	IB120012A, IB120013A, IB120014A Exp. 08/2022	Class II	Jubilant Cadista Pharmaceuticals, Inc.
Milk of Magnesia 2400 mg / 30 mL Oral Suspension	NDC: 00904-6846-73	20071A Exp. 07/2022	MW	Plastikon Healthcare, LLC
Milk of Magnesia 2400 mg / 10 mL Oral Suspension	NDC: 00904-6840-72	20074A Exp. 07/2022	MW	Plastikon Healthcare, LLC
Magnesium Hydroxide 1200 mg / Aluminum Hydroxide 1200 mg / Simethicone 120 mg per 30 mL Oral Suspension	NDC: 00904-6838-73	21103A, 21095A, 21096A, 21099A Exp. 09/2023; 20046A Exp. 05/2022; 20076A Exp. 07/2022 20079A, 20080A, 20081A Exp. 08/2022; 21057A, 21059A 05/2023; 21115A 10/2022	MW	Plastikon Healthcare, LLC
Magnesium Hydroxide 2400 mg / Aluminum Hydroxide 2400 mg / Simethicone 240 mg per 30 mL Oral Suspension	NDC: 00904-6839-73	20051A Exp. 08/2022; 20088A Exp. 09/2022	MW	Plastikon Healthcare, LLC
Naftifine Hydrochloride 1% Gel	NDC: 00115-1510-48; 00115-1510-63; 00115-1510-58	12070A Exp. 05/2023; 11801A, 11800A Exp. 09/2022; 12386A Exp. 08/2023; 11940A Exp. 12/2022	Class II	Tolmar, Inc.
Matzim LA (Diltiazem Hydrochloride) 180 mg Extended-Release Tablets	NDC: 52544-0691-30	1411593A Exp. 09/2022	Class II	Teva Pharmaceuticals USA Inc
Matzim LA (Diltiazem Hydrochloride) 240 mg Extended-Release Tablets	NDC: 58544-0691-30	1411596A Exp. 09/2022	Class II	Teva Pharmaceuticals USA Inc
Telmisartan and Hydrochlorothiazide 80 mg/25 mg Tablets	NDC: 68462-0842-13	17210935, 17210936 Exp. 05/2023 17211206 Exp. 06/2023 17211652, 17211655, 17211658 Exp. 08/2023	Class II	Glenmark Pharmaceuticals Inc., USA
Telmisartan and Hydrochlorothiazide 80 mg/12.5 mg Tablets	NDC: 68462-0841-13	17210929, 17210930 Exp 05/2023; 17211203 Exp. 06/2023; 17211643, 17211646, 17211649 Exp. 08/2023	Class II	Glenmark Pharmaceuticals Inc., USA
Triple Antibiotic Ointment, Bacitracin zinc, Neomycin	NDC: 00498-0750-36	Part# 231209G	Class II	Mckesson Medical-Surgical



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sulfate, Polymixin B sulfate, First Aid Antibiotic, Triple Antibiotic Ointment, 144 packets per box, Net wt. per packet 0.5 g				Inc. Corporate Office
Bisacodyl Suppositories, Fast Acting Stimulant Laxative, 100 suppositories per box, 10 mg each	NDC: 57896-0443-01	Part# 444-01-HST	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Naphcon A eye drops, Naphazoline HCl 0.025% and Pheniramine Maleate 0.3%, Redness Reliever and Antihistamine Eye Drops, Sterile, 15 mL (0.5 FL OZ) bottle per box	NDC: 00065-0085-15	Part# 0065008515	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Systane, Lubricant Eye Drops, Polyethylene Glycol 400 0.4% Lubricant, Propylene Glycol 0.3% Lubricant, Original, Long Lasting Dry Eye Relief, Sterile	NDC: 00065-0429-15; 00065-0429-30	Part# 0065042915, 0065042930	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Eye-stream, eye wash solution, sterile, 4 FL OZ (118 mL) bottle per box	NDC: 00065-0530-04	Part# 0065053004	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Systane Balance, Lubricant Eye Drops, Propylene Glycol 0.6% lubricant, Restorative Formula, Sterile, 10 mL (1/3 FL OZ) bottle per box	NDC: 00065-1433-02	Part# 0065143302	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Systane Zaditor, ketotifen fumarate ophthalmic solution 0.035%, Antihistamine eye drops, Eye Itch Relief, up to 12 Hours, Sterile, 30 day supply, 5mL (0.17 FL OZ) bottle per box	NDC: 00065-4011-05	Part# 0065401105	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Debrox, Carbamide Peroxide, Earwax Removal Aid, 0.5 FL OZ (15 mL) bottle per box)	NDC: 63029-0321-01	Part# 04203710478	Class II	Mckesson Medical-Surgical Inc. Corporate Office



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Miralax (Polyethylene Glycol 3350), Powder for Solution, Osmotic Laxative, 30 Once-Daily Doses, Net WT 17.9 OZ (510 g) bottle	NDC: 11523-7234-04	Part# 11523723404	Class II	Mckesson Medical-Surgical Inc. Corporate Office
GenTeal Tears, Lubricant Eye Ointment, Night-Time Ointment, Sterile, 3.5 gm (0.12 FL OZ) per box	NDC: 00065-0518-01	Part# 30065051801	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Pataday, Once Daily Relief, Olopatadine hydrochloride ophthalmic solution 0.2%, Antihistamine, Eye Allergy Itch Relief, Once Daily, Sterile, 2.5 mL (0.085 FL OZ) bottle per box	NDC: 00065-8150-01	Part# 00065815001	Class II	Mckesson Medical-Surgical Inc. Corporate Office
A&D Original Ointment, Diaper Rash Ointment & Skin Protectant, 16 oz. Jar	NDC: 11523-0096-03	Not Provided	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Dakin's Solution, sodium hypochlorite 0.125%, quarter strength	NDC: 00436-0672-16	Not Provided	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Dakin's Solution, sodium hypochlorite 0.25%, half strength	NDC: 00436-0936-16	Not Provided	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Dakin's Solution, sodium hypochlorite 0.5% full strength	NDC: 00436-0946-16	Not Provided	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Asthmanefrin Racephinephrine Inhalation Solution Bronchodilator, For temporary relief of mild symptoms of intermittent asthma, Preservative Free, Sterile, For Oral Inhalation Only, 30 vials per box	NDC: 00487-2784-01	Not Provided	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Racephinephrine Inhalation Solution, USP 2.25%, Bronchodilator, For Oral Inhalation Only, Sulfite Free, Preservative Free, 30	NDC: 00487-5901-99	Not Provided	Class II	Mckesson Medical-Surgical Inc. Corporate Office



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x 0.5 mL Sterile Unit-of-Use Vials, each in a foil pouch, per carton				
Sterile Alcohol Prep Pads, Sterile, Latex Free, 100 large pads per box	NDC: 67777-0121-16	Part# 1116	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Alcohol Swabsticks, Antiseptic, 50 4" saturated individual packets per box	NDC: 67777-0300-01 (current NDC); 67777-0120-10 (discontinued)	Part# 1203	Class II	Mckesson Medical-Surgical Inc. Corporate Office
Lorazepam 2mg/mL Injection, 1 mL vial, 25 vials per carton	NDC: 00641-6044-25; 00641-6044-01	060064 Exp. 06/2023; 070084, 070126 Exp. 07/2023; 080091, 080060 Exp. 08/2023	Class II	Hikma Pharmaceuticals USA Inc.
Ativan Injection (lorazepam injection), 2mg/mL, 1 mL vial, 25 vials per carton	NDC: 00641-6001-25; 00641-6001-01	060064Z Exp. 06/2023	Class II	Hikma Pharmaceuticals USA Inc.
Lorazepam 2mg/mL Injection, 1 mL vial, 25 vial per carton	NDC: 00641-6048-25; 00641-6048-01	070088 Exp. 07/2023	Class II	Hikma Pharmaceuticals USA Inc.
Lorazepam 4mg/mL Injection, 1 mL vial, 25 vial per carton	NDC: 00641-6045-25; 00641-6045-01	070096 Exp. 07/2023	Class II	Hikma Pharmaceuticals USA Inc.
Prednisone 20 mg Tablets	NDC: 64380-0785-06	7248988B Exp. 09/2023	Class II	Strides Pharma Inc.
Fentanyl Citrate in 0.9% Sodium Chloride 1 mg per 100 mL (10 mcg per mL) IV bags	NDC: 70324-0327-01	CHI Exp. 12/22/2022	Class II	SterRx, LLC
Fentanyl Citrate in 0.9% Sodium Chloride, 2.5 mg per 250 mL, (10 mcg per mL) IV bags	NDC: 70324-0327-02	CHL Exp. 12/29/2022	Class II	SterRx, LLC
Difluprednate Ophthalmic Emulsion 0.05%, For Ophthalmic Use Only, Sterile, 5 mL bottles	NDC: 69097-341-35	DEG3LC2 Exp. 05/2023	Class II	CIPLA
PropofolInjectable Emulsion, 100 mL Single Patient Use Glass Fliptop Vial	NDC: 00409-4699-54; 00409-4699-24	EA7470 Exp. 06/01/2023	MW	Hospira, Inc., a Pfizer Company



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Rifampin 150 mg Capsules	NDC: 68180-0658-06	A200170 Exp. 12/2023	Class II	Lupin Pharmaceuticals Inc.
Fulvestrant Injection 250mg/5mL (50 mg/mL), Contains 2 Single-Dose Prefilled Syringes	NDC: 70710-1688-08	B200076 Exp. 01/31/2024	Class II	Zydus Pharmaceuticals (USA) Inc
Prednisolone 15 mg per 5 mL Oral Solution, 240 ml bottle	NDC: 50383-0042-24	379804 Exp. 08/31/2023	Class II	Akorn, Inc
Acetaminophen Injection, 10 mg/mL, 1,000 mg/100 mL, 100 mL VIAFLO container bag, Single Dose Container, For Intravenous Use Only	NDC: 36000-0306-60	20K19G64T1 Exp. 10/31/2022; 21K23G65, 21K25G65, 21K26G65, 21K29G67 Exp. 10/31/2023; 21L10G65, 21L13G66, 21L14G66, 21L15G65 Exp. 11/30/2023	Class II	Baxter Healthcare Corporation
Ketorolac Tromethamine Injection, 60 mg/2 mL (30 mg/mL), packaged in 2 mL single dose vials	NDC: 00487-6232-01	023011 Exp. 08/31/2022	Class II	Nephron Sc Inc
PF-Neostigmine Methylsulfate Injection, USP, 3 mg/3 mL (1 mg/mL), One 3 mL Unit-Dose Vial, packaged in 30 x 3 mL Sterile Unit-Dose Vials per carton	NDC: 69374-0932-33	NE1057A Exp. 10/23/2022	Class II	Nephron Sterile Compounding Center LLC
Trisodium Citrate 0.5% Solution, (0.5%/4L), contains Per Liter: Sodium 140 mmol/L, Chloride 86 mmol/L, Citrate 18 mmol/L, 4000 mL IV bag, packaged in 1 x 1 IV bag per carton	NDC: 69374-0910-04	TC2007D Exp. 08/26/2022; TC2010A Exp. 09/25/2022	Class II	Nephron Sterile Compounding Center LLC
PF-0.125% Bupivacaine HCl Injection, 625 mg/500 mL (1.25 mg/mL), 500 mL bag, packaged in 10 x 1 IV Bag per case	NDC: 69374-0970-05	BH2003A Exp. 08/19/2022; BH2011A Exp. 11/9/2022	Class II	Nephron Sterile Compounding Center LLC
PF-Labetalol HCl Injection, 20 mg/4 mL (5 mg/mL), One 4 mL Unit-Dose Vial, packaged in 30 x 4 mL	NDC: 69374-0946-34	LB2005A Exp. 03/02/2023	Class II	Nephron Sterile Compounding Center LLC



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Sterile Unit-dose Vials per carton				
Divalproex Sodium 250 mg Extended Release Tablets	NDC: 65162-0755-10	AR210705 Exp. 04/2024	Class II	Amneal Pharmaceuticals of New York, LLC

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

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 Safety Resources:
<https://ww3.iehp.org/en/providers/pharmaceutical-services/clinical-information/safety-resources/>

If you have any questions or comments regarding this recall, please call IEHP Pharmaceutical Services Department at 909-890-2049, 8am – 5pm (PST), Monday through Friday.

Sincerely,

IEHP Pharmaceutical Services