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Inland Empire Health Plan

# PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

January 5, 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
Diclofenac Sodium Topical Solution, 1.5 w/w, 5 fl oz (150 mL) plastic bottles	NDC: 52665-0002-05	15188 Exp. 02/2023	Class II	Teligent Pharma, Inc.
Diclofenac Sodium Topical Solution, 1.5 w/w, 5 fl oz (150 mL) plastic bottles	NDC: 52665-0025-05	15028 Exp. 01/2023; 15379 Exp. 03/2023.	Class II	Teligent Pharma, Inc.
Enoxaparin Sodium 40 mg/0.4 mL Injection	NDC: 00781-3246-64	SAB06761A Exp. 04/2023	MW	Sandoz, Inc.
Veklury® (remdesivir 100mg for injection)	NDC: 61958-2901-02	2141001-1A, 2141002-1A Exp. 01/2024	MW	Gilead Sciences Inc.
Aluminum Potassium Sulfate Concentrated (Pf) 300 G/300 MI	NDC: 05446-0637-03	All Lots	MW	Edge Pharma, LLC
Buffered Lidocaine Hcl (Pf) 1%	NDC: 05446-0850-10	All Lots	MW	Edge Pharma, LLC
Buffered Lidocaine Hcl / Epinephrine Solution (Pf) 1% / 1:100,000	NDC: 05446-1268-01	All Lots	MW	Edge Pharma, LLC
Ceftazidime (Pf) 22.5 Mg/MI	NDC: 05446-0733-01	All Lots	MW	Edge Pharma, LLC
Cefuroxime Ophthalmic Solution (Pf) 10 Mg/MI	NDC: 05446-1003-01	All Lots	MW	Edge Pharma, LLC
Dexamethasone Phosphate (Pf) 24 Mg/MI	NDC: 05446-0848-01	All Lots	MW	Edge Pharma, LLC
Edetate Disodium (Edta) (Pf) 1.5%	NDC: 05446-1427-10	All Lots	MW	Edge Pharma, LLC
Edetate Disodium (Edta) (Pf) 3%	NDC: 05446-1428-10	All Lots	MW	Edge Pharma, LLC

10801 6<sup>th</sup> St., Suite 120, Rancho Cucamonga, CA 91730

Tel (909) 890-2049 Fax (909) 890-2058

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Epinephrine / Lidocaine Hcl (Pf) 0.025% / 0.75%	NDC: 05446-0863-01	All Lots	MW	Edge Pharma, LLC
Gemcitabine (Pf) 20 Mg/MI	NDC: 05446-1566-50	All Lots	MW	Edge Pharma, LLC
Glycerin, Sterile (Pf) 99%	NDC: 05446-1486-03	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Bupivacaine Hcl / Hyaluronidase (Pf) 2% / 0.375% / 15 Units/MI	NDC: 05446-1548-18	All Lots	MW	Edge Pharma, LLC
Methacholine Challenge 5 Syringe Test Kit	NDC: 05446-1600-05	All Lots	MW	Edge Pharma, LLC
Methacholine Chloride (Pf) 16 Mg/MI	NDC: 05446-1241-01	All Lots	MW	Edge Pharma, LLC
Methacholine Chloride (Pf) 4 Mg/MI	NDC: 05446-1246-01	All Lots	MW	Edge Pharma, LLC
Methacholine Chloride (Pf) 1 Mg/MI	NDC: 05446-1247-01	All Lots	MW	Edge Pharma, LLC
Methacholine Chloride (Pf) 0.25 Mg/MI	NDC: 05446-1248-01	All Lots	MW	Edge Pharma, LLC
Methacholine Chloride (Pf) 0.0625 Mg/MI	NDC: 05446-1249-01	All Lots	MW	Edge Pharma, LLC
Methotrexate (Pf) 125 Mg/5MI	NDC: 05446-1505-05	All Lots	MW	Edge Pharma, LLC
Mitomycin Irrigation (Pf) 1 Mg/MI	NDC: 05446-1416-01	All Lots	MW	Edge Pharma, LLC
Mitomycin-C (Pf) 0.4 Mg/MI	NDC: 05446-1009-01	All Lots	MW	Edge Pharma, LLC
Mitomycin-C (Pf) 0.2 Mg/MI	NDC: 05446-1011-01	All Lots	MW	Edge Pharma, LLC
Moxifloxacin Hcl (Pf) 1 Mg/MI	NDC: 05446-1050-01	All Lots	MW	Edge Pharma, LLC
Mvasi 3.75Mg/0.15MI (25 Mg/MI)	NDC: 05446-1661-13	All Lots	MW	Edge Pharma, LLC
Neostigmine Methylsulfate 1 Mg/MI	NDC: 05446-1549-05	All Lots	MW	Edge Pharma, LLC
Norepinephrine Bitartrate 8 Mg/250MI	NDC: 05446-1179-03	All Lots	MW	Edge Pharma, LLC
Phenol, Sterile (Pf) 6%	NDC: 05446-1476-05	All Lots	MW	Edge Pharma, LLC
Phenylephrine / Tropicamide / Ketorolac / Ciprofloxacin (Pf) 10% / 1% / 0.125% / 0.3%	NDC: 05446-1270-01	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl 0.1 Mg/MI	NDC: 05446-1544-10	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl 0.1 Mg/MI	NDC: 05446-1545-05	All Lots	MW	Edge Pharma, LLC



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Phenylephrine Hcl (Pf) 800 Mcg/10 MI	NDC: 05446-1652-01	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl (Pf) 20 Mg/ 250 MI	NDC: 05446-1667-01	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl / Lidocaine Hcl (Pf) 1.5% / 1%	NDC: 05446-1118-01	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl / Tropicamide 2.5% / 1%	NDC: 05446-0815-01	All Lots	MW	Edge Pharma, LLC
Phenylephrine/ Cyclopentolate / Tropicamide / Ketorolac 10% / 0.25% / 0.25% / 0.125%	NDC: 05446-0859-03	All Lots	MW	Edge Pharma, LLC
Phenylephrine/ Cyclopentolate / Tropicamide / Ketorolac (Pf) 2.5% / 0.25% / 0.25% / 0.125%	NDC: 05446-0993-01	All Lots	MW	Edge Pharma, LLC
Benzocaine / Lidocaine / Tetracaine 20% / 8% / 4%	NDC: 05446-1235-01	All Lots	MW	Edge Pharma, LLC
Cantharidin 0.7%	NDC: 05446-0572-03	All Lots	MW	Edge Pharma, LLC
Cantharidin Plus 1% / 30%	NDC: 05446-0970-03	All Lots	MW	Edge Pharma, LLC
Ciprofloxacin / Sulfacetamide Sodium / Amphotericin B 30Mg / 50Mg / 5Mg	NDC: 05446-1633-01	All Lots	MW	Edge Pharma, LLC
Ciprofloxacin / Sulfacetamide Sodium / Amphotericin B /	NDC: 05446-1634-01	All Lots	MW	Edge Pharma, LLC
Hydrocortisone 30Mg / 50Mg / 5Mg / 25Mg	NDC Not Provided	All Lots	MW	Edge Pharma, LLC
Dexamethasone Iontophoresis 0.4%	NDC: 05446-0622-01	All Lots	MW	Edge Pharma, LLC
Dibutyl Squarate 2%	NDC: 05446-1047-03	All Lots	MW	Edge Pharma, LLC
Dibutyl Squarate 1%	NDC: 05446-1156-03	All Lots	MW	Edge Pharma, LLC
Lidocaine / Tetracaine 23% / 7%	NDC: 05446-1647-01	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Epinephrine / Tetracaine Hcl (Let) 4%/0.05%/0.5%	NDC: 05446-0607-01	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Oxymetazoline 4% / 0.05%	NDC: 05446-1256-01	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Prilocaine Hcl / Tetracaine Hcl	NDC: 05446-0790-10	All Lots	MW	Edge Pharma, LLC



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(Profound) Dental (Raspberry Marshmallow) 10% / 10% / 4%	NDC Not Provided	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Prilocaine Hcl / Tetracaine Hcl	NDC: 05446-0407-10	All Lots	MW	Edge Pharma, LLC
(Profound) Dental Gel (Mint) 10% / 10% / 4%	NDC Not Provided	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Prilocaine Hcl / Tetracaine Hcl /	NDC: 05446-1018-10	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl (Profound-Pe) Dental (Raspberry Marshmallow) 10% / 10% / 4% / 2%	NDC Not Provided	All Lots	MW	Edge Pharma, LLC
Lidocaine Hcl / Prilocaine Hcl / Tetracaine Hcl /	NDC: 05446-0408-10	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl (Profound-Pe) Dental Gel (Mint) 10% / 10% / 4% / 2%	NDC Not Provided	All Lots	MW	Edge Pharma, LLC
Phenol 89%	NDC: 05446-1211-03	All Lots	MW	Edge Pharma, LLC
Phenylephrine Hcl / Lidocaine Hcl 1% / 4%	NDC: 05446-1045-03	All Lots	MW	Edge Pharma, LLC
Phytonadione (Vitamin K) 5 Mg/MI	NDC: 05446-1132-03	All Lots	MW	Edge Pharma, LLC
Promethazine Hcl 25 Mg / 1.2MI	NDC: 05446-1341-01	All Lots	MW	Edge Pharma, LLC
Tetracaine Hcl 4%	NDC: 05446-1195-03	All Lots	MW	Edge Pharma, LLC
Vancomycin Hcl 125 Mg / 2.5MI (50 Mg/MI)	NDC: 05446-1348-01	All Lots	MW	Edge Pharma, LLC
Lidocaine Hydrochloride Topical Solution 4% (40 mg/mL), 50mL bottle	NDC: 63739-997-64	15594 Exp. 05/2023; 16345 Exp. 01/2024	MW	Teligent Pharma, Inc.
Methylcobalamin Solution for Injection, 1 mg/mL, 30 mL Multiple Dose Vial, For IM, SC or IV Use Only	NDC: 72833-0565-30	082921565 BUD: 02/25/2022	Class II	ASP CARES
Biotin Solution for Injection, 10 mg/mL, 30 mL Multiple Dose Vial, Sterile, For IM or IV use only	NDC: 72833-0589-30	091721589 BUD: 03/16/2022	Class II	ASP CARES
Ascorbic Acid Solution for Injection, 500 mg/mL, 50 mL Multiple Dose Vial, For IM, IV or SC Use Only	NDC: 72833-0690-50	092321690 BUD: 03/22/2022; 093021690 BUD: 03/29/2022	Class II	ASP CARES



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5% Dextrose Injection, USP, 50 mL ADD-Vantage Unit	NDC: 00409-7100-68; 00409-7100-66	4923608 Exp. 05/01/2022	Class II	Pfizer Inc.
Rompe Pecho CF	NDC Not Provided	19F88 Exp. 06/2022; 19G164 Exp. 07/2022	MW	Efficient Laboratories, Inc
Rompe Pecho DM	NDC Not Provided	19F168 Exp. 06/2022; 19G145, 19G361, 19G449, 19G491 Exp. 07/2022;	MW	Efficient Laboratories, Inc
	NDC Not Provided	19H20 Exp. 08/2022); 19J98, 19A418 Exp. 01/2022; 19E411 Exp. 05/2022	MW	Efficient Laboratories, Inc
Rompe Pecho MAX	NDC Not Provided	19G219 Exp. 07/2022	MW	Efficient Laboratories, Inc
Vancomycin 1 gram added to 250mL of 0.9% Sodium Chloride (Injection for Intravenous Use Only), 260 mL per bag (This is a Compounded Drug, Hospital/Office Use Only)	NDC: 71170-0254-25	AC-016402 Exp. 02/12/2022	Class II	Apollo Care
Hydrocodone Bitartrate and Acetaminophen 10 mg/325 mg Tablets	NDC: 31722-0943-01	21070817 Exp. 06/2023	Class II	Ascent Pharmaceuticals, Inc.
Lidocaine Hydrochloride 4% (40 mg/mL) Topical Solution, 50 mL glass bottles	NDC: 52565-0009-50	13262 Exp. 03/2022; 14217 Exp. 08/2022	Class I	Teligent Pharma, Inc.
Lidocaine Hydrochloride 4% (40 mg/mL) Topical Solution, 50 mL glass bottles	NDC: 63739-0997-64	16306 Exp. 01/2024	Class II	Teligent Pharma, Inc.
Lidocaine Hydrochloride 4% (40 mg/mL) Topical Solution, 50 mL glass bottles	NDC: 52565-0009-50	13058 Exp. 02/2022; 13768 Exp. 05/2022	Class II	Teligent Pharma, Inc.
Clindamycin and Benzoyl Peroxide 1%/5% Gel, 25 gram jars	NDC: 00781-7263-68	11557C1 Exp. 02/2022; 11552B1 Exp. 04/2022; 12206A1 Exp. 11/2022	Class II	TOLMAR, Inc.
Diclofenac Sodium Topical Solution, 1.5% w/w, packaged in 150 mL bottles	NDC: 68788-7707-01	E1220B	Class II	Preferred Pharmaceuticals, Inc.



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Methylcobalamin 12mg/ml injection, 1 mL vials	NDC Not Provided	188008 BUD 03/19/2022	Class II	Valgene Incorporated dba Cape Drugs
B-Complex, injection, 1 mL vials	NDC Not Provided	190036 BUD 12/27/2021	Class II	Valgene Incorporated dba Cape Drugs
Nitroglycerin Lingual Spray 400 mcg per spray	NDC: 45802-0210-02	150892 Exp. 10/2022; 153199 Exp. 02/2023; 156041 Exp. 04/2023	MW	Padagis
Metformin Hydrochloride 750 mg Extended-Release Tablets	NDC: 2578-0036-01	M008130, M008131, M008132, M008133 Exp. 06/2022; M010080, M010081 Exp. 07/2022; M011029, M011030, M011031, M011032, M011304 Exp. 08/2022; M013394, M013395, M013396, M013966, M013967 Exp. 09/2022; M100831, M100832 Exp. 12/2022; M100833, M100834, M101267, M102718, M102719, M102720 Exp. 01/2023; M102721, M102722, M104172, M104173, M104174, M104175, M104176 Exp. 02/2023 M105889, M105890 Exp. 03/2023	MW	Viona Pharmaceuticals, Inc.
Fexofenadine Hydrochloride 60 mg Tablets	NDC: 00904-6979-40	H00005 Exp. 01/2022; H00006 Exp. 04/2022; H00007 Exp. 07/2022	Class II	The Harvard Drug Group
Moxifloxacin, 1 mg/mL, 1mL in 2mL vial, solution for intracameral injection, 10 vials/carton	NDC: 71449-0096-42	2130958; Exp. 03/31/2022	Class II	Denver Solutions, LLC DBA Leiters Health
Rompe Pecho CF Cold & Flu Advanced Formula, 6 Fl. oz. (178 mL) bottles	NDC: 58593-0235-06	19F88 Exp. 06/2022; 19G164 Exp. 07/2022	Class II	Efficient Laboratories, Inc.



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Rompe Pecho DM, 6 Fl Oz (178 mL) bottles	NDC: 58593-0275-06	19F168 Exp. 06/2022; 19G145, 19G361, 19G449 19G491 Exp. 07/2022	Class II	Efficient Laboratories, Inc.
Rompe Pecho Ex Expectorant, packaged in a) 4 Fl. Oz. (118 mL) bottles NDC 58593-829-04 and b) 6 Fl. Oz. (178 mL) bottles	NDC: 58593-0829-06	19A418 Exp. 01/2022; 19E411 Exp. 05/2022; 19H20 Exp. 08/2022; 19J98 Exp. 09/2022	Class II	Efficient Laboratories, Inc.
Rompe Pecho Max Multi-Symptoms Maximum Strength, 8 Fl. Oz. (237 mL) bottles	NDC: 58593-0828-08	19G219 Exp. 07/2022	Class II	Efficient Laboratories, Inc.
Penicillin V Potassium for Oral Solution, 125 mg (200,000 U) per 5 mL	NDC: 00093-4125-73; 00093-4125-74	35446365A Exp. 03/2022; 35447040A Exp. 08/2022; 35447948B Exp. 03/2023; 35446318B Exp. 05/2022; 35447947A Exp. 03/2023	Class II	Teva Pharmaceuticals USA
Clobetasol Propionate 0.05% Ointment, packaged in 60 gram tubes	NDC: 51672-1259-03	AC13786 Exp. 12/2022	MW	Taro Pharmaceuticals USA, Inc

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