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Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

October 15, 2020

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
Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg per 50 mL (4 mcg per mL), for intravenous infusion, preservative free, 50 mL Single Dose Bottle	NDC: 63323-0671-05	6121853 Exp. 05/2021; 6122207 Exp. 06/2021	Class I	Fresenius Kabi USA, LLC
Heparin Sodium 2,500 units in 0.9% Sodium Chloride 500 mL, Single Dose Container for Intravenous Use (5 units/mL)	NDC: 70004-0655-44	1220019269, 1220019278 Exp. 08/21/2020; 1220019386 Exp. 08/25/2020	Class I	SCA Pharmaceuticals
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 500 mL, Single Dose Container for Intravenous Use (10 units/mL)	NDC: 70004-0650-44	1220019289 Exp. 08/21/2020.	Class I	SCA Pharmaceuticals
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 1000 mL, Single Dose Container for Intravenous Use (5 units/mL)	NDC: 70004-0650-46	1220019243 Exp. 08/20/2020; 1220019439,1220019279 , 1220019392 Exp. 08/24/2020; 1220019488 Exp. 08/26/2020	Class I	SCA Pharmaceuticals
Heparin Sodium 10,000 units in 0.9% Sodium Chloride 1000 mL, Single Dose Container for Intravenous Use (10 units/mL)	NDC: 70004-0652-46	1220019457 Exp. 08/24/2020	Class I	SCA Pharmaceuticals



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Sulfamethoxazole and Trimethoprim 800 mg/160 mg Double Strength Tablets	NDC: 65862-0420-05	STSD19109-A Exp. 05/31/2022; SP1D19083AA3, SP1D19084AA3 Exp. 08/31/2022	Class II	Aurobindo Pharma USA Inc.
Losartan Potassium 50 mg Tablets	NDC Not Provided	LOA19357A Exp. 09/2021	Class II	Hetero Labs Limited (Unit V)
Bupirone Hydrochloride 7.5 mg Tablets	NDC: 49884-7025-01	32091002 Exp. 05/2021	Class II	Par Pharmaceutical Inc.
Buprenorphine HCl 0.3 mg/mL Injection, 1 mL vial	NDC: 00143-9246-01	2005023.1, 2005024.1, 2005025.1 Exp. 02/28/2021	Class II	Hikma Pharmaceuticals USA Inc.
Metformin Hydrochloride Extended-Release 500 mg Tablets	NDC: 76385-0129-01	18641 Exp. 05/2021	Class II	BAYSHORE PHARMACEUTICALS
Metformin Hydrochloride Extended-Release 750 mg Tablets	NDC: 76385-0129-01	18657 Exp. 05/2021	Class II	BAYSHORE PHARMACEUTICALS
Nature-Throid 0.50 grain Tablets	NDC: 64727-3299-04; 64727-3299-05; 64727-3299-06; 64727-3299-10; 64727-3299-20	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 0.75 grain Tablets	NDC: 64727-3302-04; 64727-3302-05; 64727-3302-06; 64727-3302-10; 64727-3302-20	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 1.00 grain Tablets	NDC: 64727-3300-04; 64727-3300-05; 64727-3300-06; 64727-3300-10; 64727-3300-20	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 1.25 grain Tablets	NDC: 64727-3303-04; 64727-3303-05; 64727-3303-06; 64727-3303-10; 64727-3303-20;	All Lots with expiry	MW	RLC Labs, Inc



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Nature-Throid 1.50 grain Tablets	NDC: 64727-3305-04; 64727-3305-05; 64727-3305-06; 64727-3305-10; 64727-3305-20;	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 1.75 grain Tablets	NDC: 64727-3307-04; 64727-3307-05; 64727-3307-06; 64727-3307-10; 64727-3307-20	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 2.00 grain Tablets	NDC: 64727-3308-04; 64727-3308-05; 64727-3308-06; 64727-3308-10; 64727-3308-20;	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 2.50 grain Tablets	NDC: 64727-3310-04; 64727-3310-05; 64727-3310-06; 64727-3310-10; 64727-3310-20	All Lots with expiry	MW	RLC Labs, Inc
Nature-Throid 3.00 grain Tablets	NDC: 64727-3312-04; 64727-3312-05; 64727-3312-06; 64727-3312-10; 64727-3312-20	All Lots with expiry	MW	RLC Labs, Inc
WP Thyroid 0.50 grain Tablets	NDC: 64727-5450-04; 64727-5450-05; 64727-5450-06; 64727-5450-10; 64727-5450-20	All Lots with expiry	MW	RLC Labs, Inc
WP Thyroid 0.75 grain Tablets	NDC: 64727-5650-04; 64727-5650-05; 64727-5650-06; 64727-5650-10; 64727-5650-20	All Lots with expiry	MW	RLC Labs, Inc
WP Thyroid 1.00 grain Tablets	NDC: 64727-5750-04; 64727-5750-05; 64727-5750-06; 64727-5750-10; 64727-5750-20	All Lots with expiry	MW	RLC Labs, Inc



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WP Thyroid 1.25 grain Tablets	NDC: 64727-6050-04; 64727-6050-05; 64727-6050-06; 64727-6050-10; 64727-6050-20	All Lots with expiry	MW	RLC Labs, Inc
WP Thyroid 1.50 grain Tablets	NDC: 64727-5850-04; 64727-5850-05; 64727-5850-06; 64727-5850-10; 64727-5850-20	All Lots with expiry	MW	RLC Labs, Inc
WP Thyroid 1.75 grain Tablets	NDC: 64727-6150-04; 64727-6150-05; 64727-6150-06; 64727-6150-10 64727-6150-20	All Lots with expiry	MW	RLC Labs, Inc
WP Thyroid 2.00 grain Tablets	NDC: 64727-5950-04; 64727-5950-05; 64727-5950-06; 64727-5950-10; 64727-5950-20	All Lots with expiry	MW	RLC Labs, Inc
Amiodarone Hydrochloride 450 mg/9 mL (50 mg/mL) Injection	NDC: 67457-0153-99; 67457-0153-09	191207, 191221, 191223 Exp. 11/2021; 200120 Exp. 12/2021	Class I	Mylan Institutional LLC
Tranexamic Acid 1000 mg/10 mL (100 mg/mL) Injection	NDC: 67457-0197-00; 67457-0197-10	191207, 191221, 191223 Exp. 11/2021; 200120 Exp. 12/2021	Class I	Mylan Institutional LLC
Cephalexin 250 mg per 5 mL for Oral Suspension	NDC: 0093-4177-73	30310638A Exp. 01/2022	Class II	Teva Pharmaceuticals USA
Vancomycin HCL 1.5 mg	NDC: 05446-1458-01	06-2020-04@2 BUD 09-16-2020	Class II	Edge Pharma, LLC
Albuterol Inhaler (At the Retail Level only)	NDC Not Provided	All unexpired lots	Safety Alert	Perrigo Pharmaceutical Company
RIOMET ER™ (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL	NDC: 10631-019-17	AB06381 Exp. 10/2021	MW	Sun Pharmaceutical Industries
Benzodiazepine Drug Class: Drug Safety Communication - Boxed Warning Updated to Improve Safe Use	NDC Not Provided	Not Provided	Safety Alert	FDA



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Benadryl (diphenhydramine): Drug Safety Communication - Serious Problems with High Doses of the Allergy Medicine	NDC Not Provided	Not Provided	Safety Alert	FDA
Nature-Throid, 1/2 Grain, 32.5 mg (Thyroid U.S.P. 1/2 gr. (32.5 mg))/Liothyronine (T3) 4.5mcg/Levothyroxine (T4) 19mch	NDC: 68788-9283-01	L2717G Exp. 12/31/2020; B2618A Exp. 12/21/2020; C1419P Exp. 2/28/2021	Class II	Preferred Pharmaceuticals, Inc.
Nature-Throid, 3/4 Grain (48.75 mg) Thyroid U.S.P. 3/4 gr. (48.75 mg)/Liothyronine (T3) 6.75mcg/Levothyroxine (T4) 28.5mcg	NDC: 68788-6860-09	B2618E Exp. 2/28/2021	Class II	Preferred Pharmaceuticals, Inc.
Nature-Throid, 1 Grain, 65 mg (Thyroid U.S.P. 1 gr. (65mg))/Liothyronine (T3) 9mcg/Levothyroxine (T4) 38mcg	NDC: 68788-7604-09; 68788-7604-01	A0220Q, K15171 Exp. 10/31/2020	Class II	Preferred Pharmaceuticals, Inc.
Nature-Throid, 1.5 Grain, (97.5 mg), (Thyroid U.S.P. 1.5 gr. (97.5mg))/Liothyronine (T3) 13.5mcg/Levothyroxine (T4) 57mcg	NDC: 68788-7605-09	A0220R Exp. 2/28/2021	Class II	Preferred Pharmaceuticals, Inc.



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<p>Albuterol Sulfate Inhalation Aerosol, 90 mcg per actuation, 200 metered inhalations</p>	<p>NDC: 45802-0088-01</p>	<p>18MC-052, 18MC-055, 18MC-056, 18MC-057, 18MC-058, 18MC-060 Exp. 09/2020; 18MC-061, 18MC-062, 18MC-064, 18MC-065, 18MC-066, 18MC-068, 18MC-069, 18MC-070, 18MC-071, 18MC-072, 18MC-073, 18MC-074 Exp. 10/2020; 18MC-075, 18MC-076, 18MC-077, 18MC-078, 18MC-079, 18MC-080, 18MC-081, 18MC-082, 18MC-083, 18MC-084, 18MC-085 Exp. 11/2020; 18MC-095, 18MC-096, 18MC-097, 18MC-098, 18MC-099 Exp. 12/2020; 19MC-001, 19MC-002, 19MC-003, 19MC-004 Exp 1/2021; 19MC-005, 19MC-006, 19MC-007, 19MC-008, 19MC-009, 19MC-010, 19MC-011, 19MC-012, 19MC-013, 19MC-014, 19MC-015 Exp. 2/2021; 19MC-020, 19MC-041, 19MC-042, 19MC-043, 19MC-044, 19MC-045 Exp. 4/2021; 19MC-046, 19MC-047, 19MC-048, 19MC-049, 19MC-050, 19MC-051, 19MC-052 Exp. 5/2021; 19MC-053, 19MC-054, 19MC-055, 19MC-056, 19MC-057, 19MC-059, 19MC-060 Exp. 6/2021; 19MC-061, 19MC-062, 19MC-063, 19MC-064, 19MC-065, 19MC-066, 19MC-067, 19MC-068, 19MC-069, 19MC-070, 19MC-083, 19MC-084, 19MC-085 Exp. 7/2021; 19MC-087, 19MC-088, 19MC-090, 19MC-091, 19MC-092, 19MC-093, 19MC-094, 19MC-095, 19MC-096, 19MC-097, 19MC-098, 19MC-099 Exp. 8/2021; 19MC-101, 19MC-102, 19MC-103, 19MC-104, 19MC-107, 19MC-108, 19MC-109, 19MC-110, 19MC-112, 19MC-113 Exp. 9/2021; 20MC-014, 20MC-015, 20MC-016, 20MC-017, 20MC-020, 20MC-021, 20MC-072 Exp. 3/2022; 20MC-022, 20MC-023, 20MC-024, 20MC-029, 20MC-030, 20MC-032, 20MC-034, 20MC-035, 20MC-036, 20MC-037, 20MC-038, 20MC-039, 20MC-040, 20MC-041, 20MC-042, 20MC-043, 20MC-044 Exp. 4/2022; 20MC-045, 20MC-046, 20MC-047, 20MC-048, 20MC-049, 20MC-050, 20MC-051, 20MC-052, 20MC-053, 20MC-054, 20MC-061, 20MC-062, 20MC-063, 20MC-064, 20MC-065, 20MC-066, 20MC-067, 20MC-068 Exp. 5/2022; 20MC-069, 20MC-070, 20MC-078, 20MC-079, 20MC-080, 20MC-081, 20MC-083, 20MC-084 Exp. 6/2022</p>	<p>Class II</p>	<p>Perrigo Company PLC</p>
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I = Class I Recall, II = Class II Recall, MW = Market Withdrawal



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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