A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

October 03, 2019

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
Vivitrol (naltrexone for extended-release injectable suspension) 380 mg/vial and diluent per kit	NDC: 65757-0300-01	2018-3010T Exp. 8/2021	Class II	Alkermes Inc
Relpax (eletriptan HBr) tablets, 40 mg, [6-count or 12] per carton	NDC: 00049-2340-45 NDC: 00049-2340-05	AR5407 Exp. 02/2022 CD4565 Exp. 02/2022	Class II	Pfizer Inc.
Milk of Magnesia Oral Suspension 2400 mg/30 ml	NDC: 00904-6846-73	19027D, 19027E Exp. 07/2021	MW	Plastikon Healthcare
Bacteriostatic Water for Injection, 30 mL vials	NDC: 00409-3977-01 NDC: 00409-3977-03	W20308, Exp. 12/ 2019	Class II	Pfizer Inc.
AVKARE Fexofenadine Hydrochloride Tablets USP Antihistamine 180 mg, 500 Tablets per bottle	NDC: 422910-297-50	067180011A; 067180012A, Exp. 04/2021; 06718027B1 Exp. 09/2021	Class II	AVKARE Inc.
Bevacizumab, 2.5 mg/0.1 mL, Norm-Ject Syringe Intravitreal Injection, Single use only	NDC Not Provided	All lots remaining within expiry.	Class II	Pacifico National, Inc. dba AmEx Pharmacy
Bevacizumab, 1.25 mg/0.05 mL, 31G MJ Syringe Intravitreal Injection, Single use only	NDC Not Provided	All lots remaining within expiry.	Class II	Pacifico National, Inc. dba AmEx Pharmacy
20% Acetyl-L-Cysteine Ophthalmic Solutions, dispensed in 3ml dropper bottle.	NDC Not Provided	07172019@39 Exp. 8/31/19; 06192019@28 Exp. 7/03/19; 06052019@8 Exp:.6/19/19;	Class II	Compounded Solutions in Pharmacy
10% Acetyl-L-Cysteine Ophthalmic Solutions, 5ml, 10ml, 15 ml, dropper bottles	NDC Not Provided	08012019@33 Exp. 8/15/19; 07182019@66 Exp. 8/01/19; 07182019@15 Exp. 8/01/19; 07012019@46 Exp. 08/31/19; 07082019@27 Exp. 8/31/19; 07082019@55 Exp. 8/31/19; 07182019@55 Exp. 08/31/19; 06242019@55 Exp. 8/31/19; 06202019@16 Exp. 8/31/19; 08052019@11 Exp. 11/3/19	Class II	Compounded Solutions in Pharmacy

5% Acetyl-L-Cysteine Ophthalmic Solutions, 5ml, 10ml dropper bottles	NDC Not Provided	07182019@29 Exp. 8/31/19; 07082019@2 Exp. 8/31/19; 06052019@21 Exp. 08/31/19 06062019@52 Exp. 6/25/19; 07022019@28 Exp. 8/31/19	Class II	Compounded Solutions in Pharmacy
PRE-TAT (lidocaine) 3 in 1 Pre Tattoo Prep With Lidocaine Cream, 4%, packaged in 1 OZ, 2 OZ, and 4 OZ jars, OTC	NDC: 69804-0002-05 69804-0002-02 69804-0002-03	1222, Exp 06/14/2023	Class II	Ridge Properties, LLC
PRE-TAT (lidocaine) 3 in 1 Pre Tattoo Prep With Lidocaine Liquid Gel, 4%, packaged in 1 OZ, 2 OZ, 4 OZ bottles, OTC	NDC: 69804-0019-14 69804-0019-15 69804-0019-16	1213, Exp. 06/05/2023	Class II	Ridge Properties, LLC
Superior Pain & Itch Relief (lidocaine) Cream, 4%, packaged in a) 1 OZ, 2 OZ, 4 OZ jars, OTC	NDC: 69804-0070-05 69804-0070-02 69804-0070-03	1222, Exp. 06/14/2023	Class II	Ridge Properties, LLC
Superior Pain & Itch Relief (lidocaine) Liquid Gel, 4%, packaged in a) 1 OZ, 2 OZ, and 4 OZ bottles, OTC	NDC: 69804-0073-14 69804-0073-15 69804-0073-16	1213, Exp. 06/05/2023	Class II	Ridge Properties, LLC
Soothing Sore Relief (lidocaine) Cream, 4%, packaged in a) 1 OZ, 2 OZ, and 4 OZ jars, OTC	NDC: 69804-0074-05 69804-0074-02 69804-0074-03	1228, Exp. 06/21/2023	Class II	Ridge Properties, LLC
Soothing Sore Relief (lidocaine) Liquid Gel, 4%, packaged in a) 1 OZ, 2 OZ, and 4 OZ bottles, OTC	NDC: 69804-0077-14 69804-0077-15 69804-0077-16	1135, Exp. 12/27/2022	Class II	Ridge Properties, LLC
Fexofenadine Hydrochrloride Tablets 180 mg, 100-count bottle	NDC 58602-711-21	067180008A, Exp. 03/2021	Class II	Aurolife Pharma, LLC
Allergy Relief (Fexofenadine Hydrochrloride) Tablets 180 mg, packaged in 15, 30, 45-count cartons	NDC 60000-0409-53 60000-0409-30 60000-0409-48 60000-0409-45	067180025D1, 067180025B1, 067180025A1, 067180025C1, Exp. 07/2021	Class II	Aurolife Pharma, LLC
Allergy Relief (fexofenadine hydrochrloride) tablets, 180 mg, 5-count carton	NDC 46122-387-2	Not provided	Class II	Aurolife Pharma, LLC
fexofenadine hydrochloride tablets 180 mg, 150-count bottle	NDC: 68196-0976-91	067180009A, Exp. 03/21; 067180013A, 067180014A, 067180015A, Exp. 04/21; 067180018A, Exp. 05/21; 067180020A, Exp. 06/2021; 067180021A1, 067180022A1, Exp. 07/2021; 06718028A1, 06718028B1, Exp. 09/2021; 06719001A3, Exp. 01/2022	Class II	Aurolife Pharma, LLC
Fexofenadine Hydrochloride Tablets 180 mg, packaged in 15, 30-count carton	NDC: 70677-0008-02 70677-0008-01	067180016B, Exp 05/2021; 067180024F1, Exp. 07/2021	Class II	Aurolife Pharma, LLC
Allergy Relief (Fexofenadine HCl) tablets 180 mg, 15-count cartons	NDC: 49035-995-62	067180010A, Exp 03/2021; 067180023C1, 067180024D1, Exp 07/2021	Class II	Aurolife Pharma, LLC
Fexofenadine Hydrochloride Tablets 180 mg, packaged in 15, 30-count cartons	NDC: 62011-0315-01; 62011-0315-02	067180010B, Exp. 03/2021; 067180024E1, Exp 07/2021; 067180016A, Exp. 05/2021	Class II	Aurolife Pharma, LLC
Fexofenadine HCL Tablets 180 mg, 500's Brite Stock	NDC Not Provided	067180011A, 067180012A, Exp. 04/2021; 06718027B1, Exp. 09/2021	Class II	Aurolife Pharma, LLC
Allergy (Fexofenadine Hydrochloride) Tablets 180 mg, 30-count bottles	NDC: 58602-0820-09	067180026A1, Exp. 07/2021	Class II	Aurolife Pharma, LLC
Wal-Fex (Fexofenadine Hydrochloride) Tablets 180 mg, 5-count cartons	NDC: 00363-0097-55	06718027A1, Exp. 09/2021	Class II	Aurolife Pharma, LLC
Allergy (Fexofenadine Hydrochloride) Tablets 180 mg, 30-count cartons	NDC: 53943-0021-09	067180024B1, Exp. 07/2021	Class II	Aurolife Pharma, LLC

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Oxcarbazepine Oral Suspension, 300 mg/5 mL, 250 mL per bottle	NDC: 00054-0199-59	AA3957A, AA3958A, Exp. 05/2020; AA5164A, Exp. 09/2020	Class II	West-Ward Columbus Inc
Anagrelide Capsules, 0.5 mg, 100-count bottle	NDC: 13668-0453-01	BFE2E003, Exp. 08/31/2020	Class II	Torrent Pharma 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