A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

November 4, 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
Metformin HCL ER 500 mg Tablets	NDC: 49483-0623-50; 49483-0623-09; 49483-0623-10; 49483-0623-50; 49483-0623-01	E037F,E072F, E074F, D086F, G011F, E076F, XP8260, G012F Exp. 10/2020; D096F, XP8276, F001F, H029F, H031F, XP8289, Exp. 11/2020; H041F, L007F, L008F, L009F, J022F, H039F, Exp. 12/2020; J092F Exp. 01/2021; K042F Exp. 02/2021; K051F, L055F Exp. 06/2021; K079F, M001F Exp. 07/2021; A002G, A003G, A007G Exp. 08/2021; A115G, A010G, A009G Exp. 09/2021; A49001 Exp. 11/2021; A40001, A40002, XP0010, A40003, A40004, XP0016, A40005 Exp. 12/2021; A40006, A40007, A40008 Exp. 01/2022; A40009 02/2022; A40010, XP0036, A40011, A40013, A40012 Exp. 03/2022; XP0046, A40014, A40015, A40016, A40017, A40018 Exp. 04/2022;	MW	Marksans Pharma Limited

Metformin HCL ER 750 mg Tablets	NDC: 49483-0624-01	M125E, Exp. 10/2020; D001F, C084F Exp. 11/2020; F073F, E063F Exp. 01/2021; F072F Exp. 03/2021; J002F, J087F Exp. 04/2021; K080F, L056F Exp. 06/2021; M046F Exp. 07/2021; 9R9001 Exp. 10/2021; 9R9002 Exp. 11/2021; 9R0001, 9R0002, Exp. 12/2021; 9R0003, XR0016, 9R0004, 9R0005, Exp. 03/2022; 9R0006, 9R0007, Exp. 04/2022;	MW	Marksans Pharma Limited
Potassium Chloride Extended-Release Tablets, USP 8mEq (600 mg)	NDC: 64380-0860-06	7240675A Exp. 12/31/2021	Class II	Strides Inc.
Eye Itch Relief, Ketotifen Fumarate Ophthalmic Solution 0.035%, Sterile, 5 mL	NDC: 59779-0920-01	8A11A Exp. 12/2020	Class II	Akorn, Inc.
Buprenorphine Transdermal System 5 mcg/hour, 4 transdermal systems/4 disposal units per carton	NDC: 00093-3656-21; 00093-3656-40	190017 Exp. 02/2021; 190161 Exp. 08/2021	Class II	Teva Pharmaceuticals USA
pH-D Feminine Health Boric Acid Vaginal Suppositories, 24 vaginal suppositories per box	UPC: 3 49597 00044 5	2PA20021, 2PA20061; D-160, D-155, D-162; 7PA20071	Class II	pH-D Feminine Health
Riomet ER (metformin hydrochloride for extended-release oral suspension) 500 mg per 5 mL 16 oz. For Oral Use	NDC: 10631-0019-17	AB06381 Exp. 10/2021	Class II	SUN PHARMACEUTICAL INDUSTRIES INC
Losartan Pot/HCTZ 50/12.5 mg Tablets	NDC: 61919-0040-90	12DE1806 Exp. 01/31/2021	Class II	Direct Rx

Diethylpropion 25 mg Tablets	NDC: 00527-1475-01	CS19311, CS19337 Exp. 12/2020; CS20018B, CS20019, CS20037, CS20075, CS20076, CS20112, CS20169 Exp. 8/2021; CS20168, Exp 12/21; CS20199, Exp. 5/2022; CS20243, Exp. 7/2022	Class II	Calvin Scott & Company, Inc.
Diethylpropion 75 mg Tablets	NDC: 00527-1477-01	CS19192, CS19226, CS19263 Exp. 10/2020; CS19300 Exp. 7/2021; CS19338 Exp. 8/2021; CS20034 Exp. 10/21; CS20077 Exp. 1/2022; CS20165, CS20241 Exp. 4/2022	Class II	Calvin Scott & Company, Inc.
Phentermine 30 mg Capsules	NDC: 00527-0597-10	CS19309, CS20098 Exp. 12/2021	Class II	Calvin Scott & Company, Inc.
Ranitidine 150 mg Tablets	NDC: 61919-0339-60; 61919-0339-90	09AU1911 Exp. 02/28/2022; 09SE1904 Exp. 03/31/2022	Class II	Direct Rx
Ranitidine 300 mg 30 Tablets	NDC: 61919-0455-30	29JA1915 Exp. 09/30/2021	Class II	Direct Rx
Losartan Potassium 100 mg 30 Tablets	NDC: 61919-0952-30	27AU1801 Exp. 02/28/2021	Class II	Direct Rx
Nature-Throid 1 GR (65 mg), Each Tablet Contains: Thyroid USP 1 GR (65 mg), Liothyronine (T3) 9 mcg, Levothyroxine (T4) 38 mcg, 100 Tablets	NDC: 43063-0819-01	J18C68 Exp. 10/31/2020	Class II	PD-Rx Pharmaceuticals, Inc.
Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): Drug Safety Communication - Avoid Use of NSAIDs in Pregnancy at 20 Weeks or Later	NDCs Not Provided	N/A	Safety Alert	FDA

Paroex Chlorhexidine Gluconate Oral Rinse, 4 oz and 16 oz	NDC: 52376-0021-02; 52376-0021-04	C191KR Exp. 07/31/2022; C170FY, C170FZ, C170GA, C170GB, C170GC, C177GP, C177GQ, C177GR Exp. 06/30/22; C191KT, C205BL, C191KU, C205BM, C191KW, C205BN, C191KX, C191KY, C198LJ, C198LK, C198LL, C198LM, C205BH, C191KS, C205BJ, C205BK Exp. 07/31/2022; C219DN, C219DP, C219DQ, C219DR, C219DS, C219DK, C219DL, C219DM Exp. 08/31/2022; C240GP, C240GQ, C240GR, C240GM Exp. 09/30/2022	MW	Sunstar Americas, Inc.
NP Thyroid 15, Thyroid 1/4 grain (15 mg) Tablets	NDC: 42192-0327-01	M327E19-1 Exp. 10/2020	Class I	Acella Pharmaceuticals, LLC
NP Thyroid 120, Thyroid 2 grain (120 mg) Tablets	NDC: 42192-0328-01	M328F19-3 Exp. 11/2020	Class I	Acella Pharmaceuticals, 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