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Inland Empire Health Plan

# PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

December 09, 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 750 mg Extended Release Tablets	NDC: 29033-0056-01	MET200101, MET200301 Exp. 05/2022	MW	Nostrum Laboratories
Metformin HCl 500 mg Extended Release Tablets	NDC: 29033-0055-01	MET100201, MET100401 Exp. 05/2022	MW	Nostrum Laboratories
Catapres (clonidine hydrochloride, USP) 0.1 mg Tablets	NDC: 00597-0006-01	761544, 859015 Exp. 01/2021; 861346, 956626 Exp. 01/2022	Class II	Boehringer Ingelheim Pharmaceuticals, Inc.
Catapres (clonidine hydrochloride, USP) 0.2 mg Tablets	NDC: 00597-0007-01	861135, C34139 Exp. 11/2021	Class II	Boehringer Ingelheim Pharmaceuticals, Inc.
Catapres (clonidine hydrochloride, USP) 0.3 mg Tablets	NDC: 00597-0011-01	954953 Exp. 01/2022	Class II	Boehringer Ingelheim Pharmaceuticals, Inc.
Hydrocortisone butyrate Cream, 0.1%, 15-gram tubes	NDC: 68682-0270-15	18125C Exp. 09/2020; 19079B Exp. 05/2021; 19142B Exp. 09/2021; 19167B, Exp. 10/2021	Class II	Bausch Health Companies, Inc.
Metformin Hydrochloride Extended Release 750 mg Tablets	NDC: 70518-2480-00	J0423350-121219 Exp. 12/31/2020 J0434828-020320 Exp. 02/28/2021 J0442511-031220 Exp. 03/31/2021 J0448429-040920 Exp. 04/30/2021 J0472499-081020, J0472532-081020 Exp. 08/31/2021	Class II	RemedyRepack Inc.



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Gluconate 0.12% Oral Rinse	NDC: 70166-0027-15	T09101A Exp. 01/2021; T08292A, T10011A Exp. 02/2021; M10193A, T10223A Exp. 03/2021	MW	Lohxa, LLC
Metformin Hydrochloride 500 mg Extended-Release Tablets	NDC: 49483-0623-09; 49483-0623-01; 49483-0623-50; 49483-0623-10	E072F, E074F, E076F Exp. 10/2020; D096F, H029F, H031F, XP8276, XP8289 Exp. 11/20202; L007F, J022F, H039F Exp. 12/2020; J092F Exp. 01/2021; L055F Exp. 06/2021; K079F Exp. 07/2021; A002G, A003G, A007G Exp. 08/2021; A49001 Exp. 11/2021; A40001, A40003, A40005 Exp. 12/2021; A40009 Exp. 02/2022; A40010, XP0036, A40013 Exp. 03/2022; A40015 Exp. 04/2022; XP8260 Exp. 10/2020; XP0010, XP0016 Exp. 12/2021; XP0046 Exp. 04/2022; E037F, G011F Oct-20; F001F Nov-20; H041F, L009F Dec-20; K051F Jun-21; A115G, A010G Sep-21; A40006, A40007, A40008 Jan-22; A40011 Mar-22; A40016, A40018 Apr-22; D086F Oct-20; G012F Nov-20; L008F Dec-20; K042F Feb-21; M001F Jul-21; A009G Sep-21; A40002, A40004 Dec-21; A40012 Mar-22, A40014, A40017 Apr-22	Class II	Marksans Pharma Limited



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<p>Metformin Hydrochloride 750 mg Extended-Release Tablets</p>	<p>NDC: 49483-0624-01</p>	<p>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</p>	<p>Class II</p>	<p>Marksans Pharma Limited</p>
<p>Chlorhexidine Gluconate 20%</p>	<p>NDC: 53296-0012-00</p>	<p>A-200301, A-200307, A- 200308, A-200309, A- 200395, A-200488, A- 200310, A-200311, A- 200315, A-200319, A- 200397, A-200398</p>	<p>Class II</p>	<p>Medichem S.A.</p>
<p>Metformin Hydrochloride 750 mg Extended-Release Tablets</p>	<p>NDC: 70934-0334-30</p>	<p>N107411901, N107411903, N107411904, N107411905, N107411906 Exp. 11/30/2020; N107411907, N107412001 Exp. 4/30/2021; N107412002, N107412004 Exp. 11/30/2021; N107412003 Exp. 7/31/2021</p>	<p>Class II</p>	<p>Denton Pharma, Inc.</p>



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<p>Metformin Hydrochloride 500 mg Extended-Release Tablets</p>	<p>NDC: 70934-0309-30; 70934-0309-60; 70934-0309-90; 70934-0309-98</p>	<p>N107051905 Exp. 10/31/2020; N107052002, N107052005 Exp. 9/30/2021; N107051907 Exp. 10/31/2020; N107052001 Exp. 06/30/2021; N107052010, N107052008, N107052004 Exp. 9/30/2021; C107051908 Exp. 10/31/2020; C107052002, C107051909 Exp. 6/30/2021; C107052001 Exp. 12/31/2020; C107052004, N107052006, N107052007, N107052009, N107052011, N107052012 Exp. 09/30/2021; C107051907, N107051904, N107051906 Exp. 10/31/2020 C107051910 Exp. 6/30/2021; C107052003, C107052005, N107052003 Exp. 09/30/2021</p>	<p>Class II</p>	<p>Denton Pharma, Inc.</p>
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Metformin Hydrochloride 500 mg Extended-Release Tablets	NDC: 72789-0009-30; 72789-0009-60; 72789-0009-90; 72789-0009-93	B20D23, B20D67 Exp. 07/31/2021; C20D55 Exp. 12/31/2021; A20D92, A20F59, B20C16 Exp. 07/31/2021; C20D63, D20A45, D20C80 Exp. 12/31/2021 G20D46, I20C57 Exp. 04/30/2022; A20D90, A20E77, A20F69, B20F43 Exp. 07/31/2021; C20B14, D20A41 Exp. 12/31/2021; I20D94, I20E56, J20A28 Exp. 04/30/2022; B20B96 Exp. 07/31/2021; C20C28, C20E58, D20B17 Exp. 12/31/2021; G20D91 Exp. 04/30/2022	Class II	PD-Rx Pharmaceuticals, Inc.
Metformin Hydrochloride 750 mg Extended-Release Tablets	NDC: 43063-0902-30; 43063-0902-60	A20A97, B20D25 Exp. 04/30/2021; B20D69, C20B95, C20D60, E20A50 Exp. 07/31/2021; E20D37, E20D73 Exp. 03/31/2022; J19F04 Exp. 01/31/2021; C20C15 Exp. 07/31/2021; F20A14 Exp. 03/31/2022; L19C15 Exp. 04/30/2021	Class II	PD-Rx Pharmaceuticals, Inc.
Metformin Hydrochloride 500 mg Extended-Release Tablets	NDC: 72189-0064-90	04DE1902, 11DE1908 Exp. 06/30/2021	Class II	Direct Rx
Metformin Hydrochloride 750 mg Extended-Release Tablets	NDC: 29033-0056-01	MET200101, MET200301 Exp. 05/2022	Class II	Nostrum Laboratories Inc
Metformin Hydrochloride 500 mg Extended-Release Tablets	NDC: 29033-0055-01	MET100201, MET100401 Exp. 05/2022	Class II	Nostrum Laboratories Inc
Lansoprazole 15 mg Delayed-Release Orally Disintegrating Tablets	NDC: 68382-0771-77	M005681 Exp 03/2022	Class II	Zyodus Pharmaceuticals (USA) Inc



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Lansoprazole 30 mg Delayed-Release Orally Disintegrating Tablets	NDC: 68382-0772-77	M005682 Exp. 03/2022	Class II	Zydus Pharmaceuticals (USA) Inc
Bupivacaine Hydrochloride in 8.25% Dextrose Injection, Spinal 0.75% (15 mg/2 mL) 10 x 2 mL single- dose ampules	NDC: 36000-0092-10	A0B1241 Exp. 10/2020; A0C0091 Exp. 12/2020; A0D0268 Exp. 02/2022	Class II	Baxter Healthcare Corporation
Mesalamine 1.2 gram Delayed-Release Tablets	NDC: 00591-2245-22	1342498A Exp. 12/2020; 1342499A Exp. 01/2021; 1354638A Exp. 03/2021; 1354639A, 1358274A, 1358448A, 1364618A, 1369884A Exp. 05/2021; 1366195A, 1369885A, 1373570A Exp. 06/2021; 1373571A Exp. 07/2021; 1388571A Exp. 01/2022; 1395725A, 1396585A, 1397550A, 1399389A Exp. 04/2022; 1403885A, 1403886A Exp. 06/2022.	Class II	Teva Pharmaceuticals USA
Mesalamine 1.2 gram Delayed-Release Tablets (Once-Daily)	NDC: 42291-0564-12	26085 Exp. 07/2021; 26426 Exp. 01/2022; 26983 Exp. 04/2022; 28647 Exp. 06/2022	Class II	AVKARE Inc.
Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg /50 mL (4 mcg / mL), 50 mL fill in a 50 mL vial	NDC: 63323-0671-50	6123925 Exp. 03/2022	MW	Fresenius Kabi USA
Sodium Chloride Injection, USP, 0.9%, 0.308 mOsmol/mL, 2mL Single Dose Vial, Preservative Free	NDC: 00641-0497-17; 00641-0497-25	078338 Exp. 07/2021; 088391 Exp. 08/2021; 098340 Exp. 09/2021; 108325 Exp. 10/2021; 010018 Exp. 01/2023; 068322 Exp. 06/2021	Class II	Hikma Pharmaceuticals USA Inc.
Metformin HCl 500 mg Extended Release Tablets	NDC: 68788-6932-01	E0620F Exp.12/31/2021; G2020M Exp. 04/30/2022	Class II	Preferred Pharmaceuticals, Inc.
Aripiprazole 15 mg Tablets	NDC: 60505-2675-03; 60505-2675-08	PZ6716, PZ6715 Exp. 02/2021	Class II	Apotex Corp.



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