



A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

July 08, 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 Hydrochloride Extended-Release 500 mg Tablets	NDC: 53746-0178-01; 53746-0178-05; 53746-0178-10; 53746-0178-90; 53746-0178-Bulk; 65162-0178-09; 65162-0178-10; 65162-0178-11; 65162-0178-50;	All lots with expiry	MW	Amneal Pharmaceuticals LLC
Metformin Hydrochloride Extended-Release 750 mg Tablets	NDC: 53746-0179-01; 53746-0179-Bulk; 65162-0179-10;	All lots with expiry	MW	Amneal Pharmaceuticals LLC
Doxycycline Hyclate 100 mg Tablets	NDC: 00143-2112-50; 00143-2112-05	71726A Exp. 6/2020; 71846B, 71853A Exp. 6/2021	Class II	West-Ward Columbus Inc



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Doxycycline Hyclate 100 mg Tablets	NDC: 55289-0866-06; 55289-0866-10; 55289-0866-14; 55289-0866-20; 55289-0866-28; 55289-0866-30; 55289-0866-60; 55289-0866-98; 55289-0866-71; 55289-0866-87; 55289-0866-74	I18B83, H18B11, I18A53, H18F60, I18C26, I18D61, I18D07, H18E18, I18E80, F18E11, G18E66, H18E72, H18E76 Exp. 06/30/2020; A19D44 Exp. 08/31/2020 I18F94, I18E75, I18E95, I18F64, I18F21 Exp. 09/30/2020; J18F97, J18B80, J1E02, J18E62, J18E42, J18C84 Exp. 10/31/2020; K18A33, K18D17, K18C97, K18E98, K18E92, K18A19 Exp. 11/30/2020; L18B72, L18A11, L18A29, L18D81, L18B30, L18D25, L18E50, L18C54, L18B56, L18B91 Exp. 12/31/2020; A19B70 Exp. 01/31/2021;	Class II	PD-Rx Pharmaceuticals, Inc.
LidoPatch (lidocaine HCl 3.6%, menthol 1.25%) Pain Relief Patch	NDC: 10882-0527-01; 10882-0527-02; 10882-0527-04	180103 Exp. 01/02/2021; 180104 Exp. 01/03/2021; 180105 Exp. 01/04/2021; 180106 Exp. 01/05/2021; 180107 Exp. 01/06/2021	Class II	Wuhan Bingbing Pharmaceutical Co., Ltd.
LidoPro (lidocaine 4%, menthol 5%, methyl salicylate 4%) patch	NDC: 53225-1023-01	170527 Exp. 05/2020	Class II	Wuhan Bingbing Pharmaceutical Co., Ltd.
Mencaine (lidocaine 4.5%, menthol 5%) Patch	NDC: 53225-1090-01	170731 Exp. 07/2020; 180504 Exp. 05/2021	Class II	Wuhan Bingbing Pharmaceutical Co., Ltd.
Maximum Strength Lidocaine Cold & Hot Patch (lidocaine 4%, menthol 1%)	NDC: 66902-0218-05	170614 Exp. 06/13/2020; 180108 Exp. 01/07/2021; 180109 Exp. 01/08/2021; 180110 Exp 01/09/2021; 180111 Exp. 01/10/2021; 180112 Exp. 01/11/2021; 180113 Exp. 01/12/2021; 180317 Exp 03/16/2021; 180318 Exp. 03/17/2021	Class II	Wuhan Bingbing Pharmaceutical Co., Ltd.
Metformin Hydrochloride Extended-Release 500 mg Tablets	NDC: 49483-0623-01	XP9004 Exp. 12/2020	MW	Marksans Pharma Limited, India



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Metformin Hydrochloride Extended-Release 500 mg Tablets	NDC: 60505-0260-01	All lots with expiry	MW	Apotex Corp
NP Thyroid 30, Thyroid 1/2 grain (30 mg) Tablets	NDC: 42192-0329-01	M329H18-1 Exp. 07/2020; M329J18-1, M329J18-2, M329J18-3 Exp. 08/2020; M329M18-2 Exp. 11/2020; M329A19-1 Exp. 12/2020	Class I	Acella Pharmaceuticals, LLC
NP Thyroid 60, Thyroid 1 grain (60 mg) Tablets	NDC: 42192-0330-01	M330J18-2A, M330J18-3 Exp. 08/2020	Class I	Acella Pharmaceuticals, LLC
NP Thyroid 90, Thyroid Tablets 1 & 1/2 grain (90 mg)	NDC: 42192-0331-01	M331G18-1 Exp. 06/2020; M331J18-1, M331J18-2, Exp. 08/2020; M331M18-1, M331M18-2 Exp. 11/2020	Class I	Acella Pharmaceuticals, LLC
Estriol Micronized 5 G	NDC: 71092-9977-02	17010401181119190927, 17010401181119190927 25200122 Exp. 12/2020	Class II	Triova Pharmaceuticals Llc
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Amphetamine Salts Product), 5 mg	NDC: 00555-0971-02	42614718 Exp. 02/2021	Class II	Teva Pharmaceuticals USA
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Amphetamine Salts Product), 15 mg	NDC: 00555-0777-02	42617008 Exp. 10/2021	Class II	Teva Pharmaceuticals USA
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Amphetamine Salts Product), 20 mg	NDC: 00555-0973-02	42617891 Exp. 01/2022	Class II	Teva Pharmaceuticals USA



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Doxycycline Hyclate 100 mg Tablets	NDC: 00904-0430-04; 00904-0430-06	R00732D Exp. 05/2020; R00783D Exp. 06/2020; R00828D, R00827D Exp. 08/2020;	Class II	The Harvard Drug Group
Metformin Hydrochloride Extended-Release 500 mg Tablets	NDC: 68180-0336-07	G901203 Exp. 12/2020	MW	Lupin Pharmaceuticals, Inc
Ketorolac Tromethamine 30 mg per mL Injection	NDC: 63323-0162-00; 63323-0162-01	6118737, 6118902 Exp. 04/2020; 6119052 Exp. 05/2020; 6119752 Exp. 08/2020; 6122349 Exp. 07/2021; 6122538 Exp. 09/2021	Class I	Fresenius Kabi USA, LLC
Ketorolac Tromethamine 60 mg per 2 mL (30 mg per mL) Injection	NDC: 63323-0162-03; 63323-0162-02	6119229, 6119273 Exp. 06/2020; 6119843 Exp. 09/2020; 6121115 Exp. 02/2021; 6121451, 6121452, 6121496 Exp. 03/2021	Class II	Fresenius Kabi USA, LLC
Doxycycline Hyclate 100 mg Tablets	NDC: 62584-0693-21; 62584-0693-11	179605 Exp. 06/30/2020; 181105 Exp. 08/31/2020; 183019 Exp. 01/31/2021	Class II	American Health Packaging
Unasyn (ampicillin sodium/sulbactam) 1.5 g* per vial for injection	NDC: 00049-0013-81; 00049-0013-83	3301612 Exp. 02/2022	Class II	Pfizer Inc.
Lisinopril 5 mg Tablets	NDC: 68180-0513-03	Q900683 Exp. 10/31/2022	Class II	Lupin Pharmaceuticals Inc.
Oxytocin 30 Units/500 mL (0.06 Units/mL) added to 0.9% Sodium Chloride Injection for IV Use	NDC: 70092-1068-07	30010515	Class II	QuVa Pharma, Inc.
Children's Robitussin Honey Cough and Chest Congestion DM	NDC: 00031-8760-12	02177, 02178 Exp. 01/2022	MW	GSK Consumer Healthcare
Children's Dimetapp Cold and Cough	NDC: 00031-2234-19	CL8292 Exp. 09/2021	MW	GSK Consumer Healthcare
Gaviscon Regular Strength Liquid Antacid Cool Mint, 6 FL OZ (177 mL)	NDC: 00135-0094-42	8M17C1 Exp. 11/30/2020; 9E30C1, 9F05C1 Exp. 4/30/2021	Class II	Glaxosmithkline Consumer Healthcare Holdings
Gaviscon Regular Strength Liquid Antacid Cool Mint, 12 FL OZ (355 mL)	NDC: 00135-0094-41	8H21C1 Exp. 7/31/2020; 9B25C1 Exp. 1/31/2021; 9D02C1 Exp. 2/28/2021; 9G01C1 Exp. 5/31/2021	Class II	Glaxosmithkline Consumer Healthcare Holdings



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<p>Gaviscon Extra Strength Liquid Antacid Extra Strength Cherry, 12 FL OZ. (355 mL)</p>	<p>NDC: 00135-0574-41</p>	<p>0A26C1 Exp. 12/31/2021; 0B10C1 Exp. 1/31/2022; 8L19C1, 8L27C1 Exp. 10/31/2020; 9A28C1 Exp. 12/31/2020; 9B18C1 Exp. 1/31/2021; 9C19C1 Exp. 2/28/2021; 9D09C1 Exp. 3/31/2021; 9F20C1 Exp. 5/31/2021; 9G24C1 Exp. 6/30/2021; 9J09C1 Exp. 8/31/2021; 9K29C1, 9L05C1 Exp. 9/30/2021</p>	<p>Class II</p>	<p>Glaxosmithkline Consumer Healthcare Holdings</p>
<p>Gaviscon Liquid Antacid Extra Strength, Cool Mint, 12 FL OZ (355 mL)</p>	<p>NDC: 00135-0095-41</p>	<p>0A21C1, 0A31C1, 0B05C1 Exp 12/31/2021; 8J04C1 Exp. 7/31/2020; 8L05C1 Exp. 9/30/2020; 8L13C1 Exp. 10/31/2020; 9A14C1, 9A21C1, 9B04C1 Exp. 12/31/2020; 9B11C1, 9C04C1 Exp. 1/31/2021; 9C12C1, 9C25C1 Exp. 2/28/2021; 9D17C1, 9D24C1, 9E01C1, 9E10C1 Exp. 3/31/2021; 9E21C1 Exp. 4/30/2021; 9F11C1 Exp. 5/31/2021; 9G15C1, 9G30C1, 9H06C1 Exp. 6/30/2021; 9H12C1, 9H20C1, 9H26C1 Exp. 7/31/2021; 9J23C1, 9J30C1, 9K08C1 Exp. 8/31/2021; 9L11C1, 9L18C1, 9M02C1 Exp. 10/31/2021; 9M09C1, 9M17C1 Exp. 11/30/2021; 19N1587221 Exp. 7/31/2020; 19N1743754 Exp. 12/31/2020; 19N1948440, 19N1958219 Exp 6/30/2021; 20N2019997 Exp. 7/31/2021; 20N2026258, 20N2057778 Exp. 8/31/2021</p>	<p>Class II</p>	<p>Glaxosmithkline Consumer Healthcare Holdings</p>



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Metformin Hydrochloride Extended-Release 500 mg Tablets	NDC: 60505-0260-01	All lots remaining within expiry	Class II	Apotex Inc.
Metformin Hydrochloride Extended-Release 750 mg Tablets	NDC: 42291-0611-90; 42291-0611-18; 42291-0611-50	23069 Exp. 11/30/2020; 24571 Exp. 05/31/2021; 25310 Exp. 07/31/2021; 26391 Exp. 01/31/2022; 22542 Exp. 06/30/2020; 23345 Exp. 11/30/2020; 24032 Exp. 03/31/2021; 24624 Exp. 07/31/2021; 24631 Exp. 05/31/2021; 25381 Exp. 08/31/2021; 25907 Exp. 10/31/2021; 26478 Exp. 01/31/2022; 22348, 22405, 22406, 22740 06/30/2020; 23346 Exp. 11/30/2020; 23926 Exp. 03/31/2021; 24364 Exp. 05/31/2021; 25014 Exp. 07/31/2021; 25334 Exp. 09/30/2021; 25906 Exp. 10/31/2021; 26392 Exp. 01/31/2022	Class II	AVKARE Inc.



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<p>Metformin Hydrochloride Extended-Release 500 mg Tablets</p>	<p>NDC: 50268-0531-15; 42291-0610-90; 42291-0610-18; 42291-0610-36; 42291-0610-10</p>	<p>23537, 23613, 24083, 24291, 24725, 22073, 22202, 22430 Exp. 06/30/2020; 22460, HH01618A, HH01718A, HH01818A, HH01918A Exp. 07/31/2020; 22539, 22540, 22541, 22538, 22638, 22639 Exp. 09/30/2020; HK09818A, HK09918A, HK10018A, HK10118A, HK10218A Exp. 10/31/2020; HK13618A Exp. 11/30/2020; 23299, 23300, 23484, 26322, 23293, 23475, 23292, 23291, 23344, 23631 Exp. 01/31/2021; 23917, 23658, 23979, 23707, 23706, HB10419A, HC00119A, HC00219A, HC00319A, HC00419A Exp. 03/31/2021; HD01619A, HD01719A, HD01819A, HD01919A, HD02019A, HD09319B, HD09419A, HD09519A, HD09619A, HD09719A, HD09819A, HD09919A, HE00919A, HE01019A, HE01119A Exp. 04/30/2021; 24164, 24165, HE09419A, HE09519A, HE13119A, HE13219A, HE13319A, HE13419A, HE13519A, HE13619A, HE13719A, HE13819A, HE13919A, HE14019A, HF01919A, HF02019A, HF02119A Exp. 05/31/2021; 25637, 24477, 24514, 24303, 24476, 24550, 24340, 24474, 24475, 24548 Exp. 06/30/2021; 25751, 24804, 24738, 24739, 24905, HG06019A, HG06119A, HG06219A, HG06319A, HG06419A, HG06519A, HG06619A, HG06719A, HG06819A, HG06919A Exp. 07/31/2021; 24945, 25380, 24906, 25379, 25378, HH02018A, HH05018A, HH05118A, HH05218A, HH05318A, HH05418A, HH05518A, HH05618A, HH05718A, HH05818A, HH05918A, HH06018A, HH06118A, HH06218A, HH06318A, HH06418A, HH03419A, HH03519A, HH03619A, HH03719A, HH03819A, HH03919A, HH04019A, HH04119A, HH04219A, HH04319A, HH08319A, HH08419A, HH08519A, HH08619A, HH08719A, HH08819A, HH08919A, HH09019A, HH09119A, HH09219A Exp. 08/31/2021; 25591, 25590, 25592, 25736, 26006, 25627, 25664 Exp. 10/31/2021; 26004, 26005, HL01119B, HL01219A Exp. 11/30/2021; 26520, 26326, 26131, 26340, HA00520A, HA00620A, HA00720A, HA00820A, HA00920A, HA01020A, HA01120A, HA01220A Exp. 01/31/2022; 26339, 26588, 26483, 26484, 26589, 26341, 26590, 26591, HB05720A, HB05820A, HB05920A, HB06020A, HB06120A, HB06220A, HB06320A, HB06420A, HB06520A, HB06620A Exp. 02/28/2022</p>	<p>Class II</p>	<p>AVKARE Inc.</p>
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Metformin HCl ER 500 mg	NDC: 43063-0428-30; 43063-0428-60; 43063-0428-90; 43063-0428-98; 43063-0428-93; 53746-0178-05	D19C80, F19C39, H19A55, H19D56, I18E0, D19A66, E19C15, F19D60, E19D32, J18B83, C19D25, C19E78, D19C60, D19D64, F19B27, G19A31, G19C41, I19A56, F19E33, I18E07, D19D56, F19A51, H19A09, H19A81, H19B16, H19B77, H19C28, I18F43, HF06618A, HF06718A Exp. 06/30/2020	Class II	PD-Rx Pharmaceuticals, Inc.
Irinotecan HCl 100mg/5mL Injection	NDC: 00143-9701-01	AC0231, AC0235 Exp. 08/2021; AC0237, Exp. 09/2021	Class II	Hikma Pharmaceuticals USA Inc.
Irinotecan HCl 100mg/5mL Injection	NDC: 00143-9583-01	AC0231A Exp. 08/2021	Class II	Hikma Pharmaceuticals USA Inc.
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 1000 mL bag (5 units/mL)	NDC: 70004-0650-46	1220017764 Exp. 06/24/2020	Class II	SCA Pharmaceuticals

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