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Inland Empire Health Plan

# PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

June 18, 2021

## 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      |
|---|--------------------------------------|---|----------------|---------------------|
| Sterile Water for Injection, 100 mL Single Dose Glass Fliptop Vial  | NDC: 00409-4887-25;<br>00409-4887-99 | DN9185 Exp. 04/01/2023  | MW             | Hospira, Inc.       |
| 0.5% Bupivacaine Hydrochloride 0.5%, 150 mg/30mL (5 mg/mL) Injection, 30 mL   | NDC: 00409-1162-19;<br>00409-1162-02 | EG6023 Exp. 07/01/2022  | MW             | Hospira, Inc.       |
| 1% Lidocaine HCl 1%, 300 mg/30 mL (10 mg/mL) Injection, 30 mL   | 00409-4279-16;<br>00409-4279-02      | EG8933 Exp. 08/01/2022  | MW             | Hospira, Inc.       |
| BD Chloraprep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.10 fl. oz. (3 ml) each          | NDC: 54365-0400-32                   | 0065386 Exp. 2/28/2023;<br>0085419, 0091666 Exp. 3/31/2023;<br>0149328 Exp. 4/30/2023;<br>0151977, 0161217 Exp. 5/31/2023;<br>0175874, 0176660,<br>0188805 Exp. 6/30/2023;<br>0211068 Exp. 7/31/2023; | Class I        | CareFusion 213, LLC |
| BD Chloraprep Hi-Lite Orange 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile Solution, 0.10 fl. oz. (3 ml) each | NDC: 54365-0400-33                   | 0107872, 0108556,<br>0148278 Exp. 04/30/2023;<br>0151978, 0155534,<br>0157085, 0160618,<br>0167907 Exp. 5/31/2023;  | Class I        | CareFusion 213, LLC |



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| <p>ChloroPrep One-Step 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution -Clear, 0.10 fl. oz. (3ml) each</p>             | <p>NDC: 54365-0400-01</p> | <p>0008777, 0016325 Exp. 12/31/2022;<br/>0021072, 0027041, 0030959, 0031090,<br/>0044735 Exp. 01/31/2023;<br/>0048062, 0052110, 0056365, 0086148<br/>Exp. 02/28/2023;<br/>0104864, 8081571, 8086851, 8087784,<br/>8095620 Exp. 03/31/2021;<br/>8106737, 8107819, 8124917, 8130509,<br/>8131816 Exp. 04/30/2021;<br/>8135646, 8141808, 8149992, 8155991,<br/>8162912, 8163900 Exp. 05/31/2021;<br/>8165721, 8176743, 8187644, 8194993,<br/>0192894, Exp. 06/30/2023;<br/>8199884, 8201565, 8205560, 8206895,<br/>8207995, 8221939 Exp. 07/31/2021;<br/>8228634, 8235981, 8247508 Exp.<br/>08/31/2021;<br/>8264554, 8289654 Exp. 09/30/2021;<br/>8299615, 8304783, 8311788, 8316776<br/>Exp. 10/31/2021;<br/>8332585, 8333924, 8337646, 8337647,<br/>8338794, 8340914 Exp. 11/30/2021;<br/>8352585, 8354835, 9007921, 9015917,<br/>9015920 Exp. 12/31/2021;<br/>9030934, 9043625, 9045819 Exp.<br/>1/31/2022;<br/>9046572, 9052554, 9059817, 9060734,<br/>9071761 Exp. 02/28/2022;<br/>9080812, 9087980, 9087982, 9088850,<br/>9092575, 9100768, 9101529, 9105675<br/>Exp. 03/31/2022;<br/>9113528, 9123753, 9130718, 9133928<br/>Exp. 04/30/2022;<br/>9135816, 9149671, 9150905, 9154935,<br/>9156866, 9165856, Exp 5/31/2022;<br/>9189224, 9194257, 9196196,<br/>9198900,9199815, 9200420 Exp.<br/>6/30/2022;<br/>9205441, 9206555 Exp. 07/31/2022;<br/>9233323, 9233645, 9236531, 9238871,<br/>9241929, 9242192, 9246940, 9246944,<br/>9249460, 9251683, 9253785, 9254193,<br/>9255899, 9257889 Exp. 08/31/2022;<br/>9261886, 9266348, 9270894, 9278673,<br/>9280666, 9284872, 9289666 Exp.<br/>09/30/2022;<br/>9291336, 9293445, 9295140, 9297772,<br/>9304891, 9305777, 9311057 Exp.<br/>10/31/2022;<br/>9316346, 9325127, 9326162, 9331792,<br/>9344775, 9345956, 9345958 Exp.<br/>11/30/2022;<br/>9350617, 9352330 Exp. 12/31/2022;</p> | <p>Class I</p>  | <p>CareFusion 213, LLC</p> |
| <p>ChloroPrep With Tint 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Hi-Lite Orange, 0.10 fl. oz. (3 ml) each</p> | <p>NDC: 54365-0400-11</p> | <p>Multiple Lots</p>   | <p>Class I</p>  | <p>CareFusion 213, LLC</p> |
| <p>BD ChloroPrep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.10 fl. oz. (3 ml) each</p>                      | <p>NDC: 54365-0400-32</p> | <p>Multiple Lots</p>   | <p>Class II</p> | <p>CareFusion 213, LLC</p> |



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| BD ChloroPrep Hi-Lite Orange 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile Solution, 0.10 fl. oz. (3 ml) each             | NDC: 54365-0400-33                   | Multiple Lots   | Class II | CareFusion 213, LLC             |
| ChloroPrep One-Step 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution -Clear, 0.10 fl. oz. (3ml) each             | NDC: 54365-0400-01                   | Multiple Lots   | Class II | CareFusion 213, LLC             |
| ChloroPrep With Tint 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Hi-Lite Orange, 0.10 fl. oz. (3 ml) each | NDC: 54365-0400-11                   | Multiple Lots   | Class II | CareFusion 213, LLC             |
| Cephalexin (Keflex) 250 mg/5mL for Oral Suspension, Pkg Size 100  | NDC: 68788-7529-01                   | B1121W Exp. 04/2022   | Class II | Preferred Pharmaceuticals, Inc. |
| Losartan Potassium 50 mg Tablets  | NDC: 43063-0854-60;<br>43063-0854-90 | E18F12, F18A12, F18F06, G18B43, G18C43, G18F75, H18D55, I18A11, I18E32, J18A90 Exp. 09/30/19;<br>J18D50, L18D01, A19B99, B19A26, B19A69 Exp. 11/30/2019   | Class II | PD-Rx Pharmaceuticals, Inc.     |
| Acetaminophen, Extra Strength, Aspirin Free, 500 MG Tablets   | NDC: 50090-5350-00                   | 323206, 323207, 323208, 335353, 335354, 335355, 335356, 335358, 335359, 335360, 335361, 335362, 335395, 352116 Exp. 07/31/2022;<br>323209, 323210, 323211, 323212, 323213, 323214, 323215, 323216, 323218, 323219, 323220, 323222, 323223, 323224, 323238, 335363, 335364, 335365, 335366, 335367, 335368, 335369, 335370, 335371, 335372, 335373, 335374, 335375, 335376, 335377 Exp. 08/31/2022 | Class I  | A-S Medication Solutions LLC.   |



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| BD ChloroPrep Hi-Lite Orange 26 mL Applicator (2% w/v chlorhexidine gluconate (CHG) and 70% v/v Isopropyl alcohol (IPA)) Sterile Solution | NDC: 54365-0400-38                   | 0108186 Exp. 4/30/2023;<br>0327867, 0327868,<br>0328213, 0338656,<br>0339071, 0328947,<br>0328949, 0329475,<br>0329477, 0330457,<br>0330955, 0330606<br>0333826, 0333852,<br>0333855, 0334119,<br>0335787, 0335792,<br>0335029, 0336506<br>0336972, 0336051,<br>0337245, 0337025,<br>0338653, 0338542,<br>0338852, 0339892<br>0339457 Exp. 11/30/2023 | Class I  | CareFusion 213, LLC                   |
| Metformin HCl 500 mg Extended-Release Tablets   | NDC: 62756-0142-02                   | JKX2749A, JKX2803A,<br>JKX2805A, JKX806A,<br>JKX2945A, JKX2946A,<br>JKX2947A, JKX2948A,<br>JKX2952A, JKX2953A,<br>JKX2954A & JKX3224A,<br>Exp 6/2032; JKX3211A,<br>JKX3212A Exp. 07/2023  | Class II | Sun Pharmaceutical Industries INC     |
| Delflex Peritoneal Dialysis Solution with 1.5% Dextrose, LM/LC, packaged in a case containing 2 x 6 Liter bags                            | NDC: 49230-0206-60                   | 20SU03019 Exp. 06/2022  | Class II | Fresenius Medical Care, North America |
| Sterile Water for Injection, 25 x 100 mL Single Dose Vials per carton   | NDC: 00409-4887-99;<br>00409-4887-25 | DN9185  | Class II | Pfizer Inc.                           |
| Metformin HCl (Generic for Glucophage XR) 500 mg Extended Release Tablets   | NDC: 68788-6932-01                   | C2520W, E0620F Exp.<br>12/31/2021;<br>G2020M, G2720A Exp.<br>4/30/2022  | Class II | Preferred Pharmaceuticals, Inc.       |
| Cefixime for Oral Suspension 100 mg/5mL, 50mL HDPE bottles  | NDC: 68180-0405-01                   | F900787 Exp. 04/2021  | Class II | Lupin Pharmaceuticals Inc.            |
| Leucovorin Calcium for Injection, equivalent to leucovorin 350 mg/vial (20 mg/mL), For IM or IV Use                                       | NDC: 00703-5145-01;<br>00703-5145-91 | 31325332B Exp. 08/2021;<br>31325756B, 31325685B<br>Exp. 09/2021   | Class II | Teva Pharmaceuticals USA              |



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| Haloperidol Decanoate 50 mg/mL Injection, 1 mL Single Dose Vials                    | NDC: 00703-7121-03 | 31325793C Exp. 09/2021                            | Class II | Teva Pharmaceuticals USA |
| Methylprednisolone Acetate 40 mg/mL Injectable Suspension, 10 mL Multiple Dose Vial | NDC: 00703-0045-01 | 31327989B Exp. 04/2021                            | Class II | Teva Pharmaceuticals USA |
| Metoclopramide 10 mg/2 mL (5 mg/mL) Injection, 2 mL Single-Use Vial                 | NDC: 00703-4502-04 | 31327989B Exp. 08/2021                            | Class II | Teva Pharmaceuticals USA |
| Haloperidol Decanoate 100 mg/mL Injection, 1 mL Single Dose Vials                   | NDC: 00703-7131-03 | 31325394C Exp. 09/2021;<br>31327161B Exp. 04/2022 | Class II | Teva Pharmaceuticals USA |

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