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Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

April 08, 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
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	NDC: 54365-0400-32	All lots including but not limited to the following lots distributed in Zone IV: 0085419 Exp. 03/31/2023; 0149328 Exp. 04/30/2023; 0161217 0151977 Exp. 05/31/2023; 0211068 Exp. 07/31/2023; 0176660, 0188805, 0175874 Exp. 06/30/2023;	Class I	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: 054365-0400-11	All lots including but not limited to the following lots distributed in Zone IV: 0038209 Exp. 01/31/2023; 0098528 Exp. 02/28/2023	Class I	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: 054365-0400-01	All lots including but not limited to the following lot distributed in Zone IV: 9080812 Exp 03/31/2022; 0192894 Exp. 06/30/2023;	Class I	CareFusion 213, LLC

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BD ChloroPrep Hi-Lite Orange 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile Solution, 0.01 fl. oz. (3 ml) each	NDC: 54365-0400-33	All lots including but not limited to the following lots distributed in Zone IV: 0107872, 0108556, 0148278 Exp. 04/30/2023; 0151978, 0155534, 0157085, 0160618, 0167907 Exp. 05/31/2023	Class I	CareFusion 213, LLC
Cisatracurium Besylate 10mg per 5mL (2 mg per mL) Injection	NDC: 71288-0712-05; 71288-0712-06	C11507A	Class I	Meitheal Pharmaceuticals Inc
Dacarbazine 200 mg Injection	NDC: 00703-5075-01; 00703-5075-03	31326582B Exp. 02/2022; 31326964B Exp. 04/2022	Class II	Teva Pharmaceuticals USA
Desmopressin Acetate 4 mcg/mL Injection	NDC: 0703-5051-01; 00703-5051-03	31326669B Exp. 03/2021	Class II	Teva Pharmaceuticals USA
Sterile Diluent for Epoprostenol Sodium for Injection	NDC: 0703-9258-01; 00703-9258-09	31326845B Exp. 03/2021; 31327844B Exp. 09/2021	Class II	Teva Pharmaceuticals USA
Epoprostenol Sodium for Injection, 0.5 mg/vial (500,000 ng)	NDC: 00703-1985-01	31327537B Exp. 09/2021	Class II	Teva Pharmaceuticals USA
Methylpredisolone Acetate Injectable Suspension USP, 40 mg/mL, 1 mL Single-Dose Vial	NDC: 00703-0031-01; 00703-0031-04	31327742B Exp. 02/2021; 31328408B Exp. 07/2021	Class II	Teva Pharmaceuticals USA
Leucovorin Calcium 100 mg/vial Injection	NDC: 00703-5140-01	31326364B Exp. 01/2022; 31327120B Exp. 05/2022; 31327963B Exp. 10/2022	Class II	Teva Pharmaceuticals USA
Metoclopramide 10 mg/2 mL (5 mg/mL) Injection	NDC: 00703-4502-01; 00703-4502-04	31325042B Exp. 06/2021; 31325336B Exp. 07/2021; 31326042B Exp. 10/2021; 31326137B Exp. 11/2021; 31326230B Exp. 12/2021; 31323816B Exp. 02/2021	Class II	Teva Pharmaceuticals USA
Toposar (etoposide) 1 gram/50 mL (20 mg/mL) injection	NDC: 00703-5657-01	31327600B Exp. 08/2022	Class II	Teva Pharmaceuticals USA



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Vecuronium Bromide for Injection, 10 mg, 1 mg/mL when reconstituted to 10 mL	NDC: 00703-2914-01; 00703-2914-03	31325712B Exp. 12/2021; 31326320B, 31326457B Exp. 02/2022; 31327880B Exp. 10/2022	Class II	Teva Pharmaceuticals USA
Epoprostenol Sodium for Injection, 1.5 mg/vial (1,500,000 ng)	NDC: 00703-1995-01	31326456B Exp. 02/28/2021	Class II	Teva Pharmaceuticals USA
Methylpredisolone Acetate 80 mg/mL Injectable Suspension	NDC: 00703-0051-01; 00703-0051-04	31327909B Exp. 04/2021; 31328352B Exp. 07/2021	Class II	Teva Pharmaceuticals USA
Methylpredisolone Acetate 400 mg/10 mL (40 mg/mL) Injectable Suspension	NDC: 00703-0045-01	31327725B Exp. 02/2021; 31327906B Exp. 03/2021	Class II	Teva Pharmaceuticals USA
Methylpredisolone Acetate 200 mg/5 mL (0 mg/mL) Injectable Suspension	NDC: 00703-0043-01	31328768B Exp. 09/2021	Class II	Teva Pharmaceuticals USA
Methylprednisolone Acetate 400 mg/5 mL (80 mg/mL) Injectable Suspension	NDC: 00703-0063-01	31327738B Exp. 03/2021	Class II	Teva Pharmaceuticals USA
Leucovorin Calcium 350 mg/vial Injection	NDC: 00703-5145-01	31324653B Exp. 03/2021; 31324480B Exp. 02/2021; 31328425B Exp. 07/2021; 31326066B Exp. 11/2021; 31326428B Exp. 02/2022; 31327396B Exp. 08/2022; 31327949B, 31327995B Exp. 10/2022; 31328031B Exp. 11/2022; 31328217B, 31328325B Exp. 12/2022;	Class II	Teva Pharmaceuticals USA
Imatinib Mesylate 100 mg Tablets	NDC: 43598-344-90; 43598-0344-31	H2000206, H2000138 Exp. 06/2022;	Class II	Dr. Reddy's Laboratories, Inc.
Irinotecan Hydrochloride 40 mg/2 mL (20 mg/mL) Injection	NDC: 59923-0714-02	7S10022A Exp. 01/2021	Class II	Areva Pharmaceuticals Inc
Fludeoxyglucose F 18 Injection, 20-300 mCi/mL at End of Synthesis (EOS) Solution	NDC: 76318-0334-50	P01-021721 Exp. 02/17/2021	Class II	The General Hospital Corporation



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Spironolactone 25 mg Tablets	NDC: 63629-1064-01; 63629-1064-02; 63629-1064-03	148969, 148791, 148991 Exp. 07/31/2022	MW	Bryant Ranch Prepack
Spironolactone 50 mg Tablets	NDC: 63629-1067-01	148992 Exp. 05/31/2022	MW	Bryant Ranch Prepack
Famotidine 40 mg Tablets	NDC: 65862-0860-99	P2000467 Exp. 07/2022	Class II	Aurobindo Pharma USA Inc.
Metoclopramide 10 mg/2 mL (5 mg/mL) Injection, 25x2mL Single Dose Vials	NDC: 00703-4502-01; 00703-4502-04	31325335B Exp. 07/2021	Class II	Teva Pharmaceuticals USA
Daytrana (methylphenidate transdermal system), Delivers 10 mg over 9 hours (1.1 mg/hr), Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton	NDC: 68968-5552-03	87579 Exp. 03/2021; 88243 Exp. 07/2021	Class II	Noven Pharmaceuticals Inc
Daytrana (methylphenidate transdermal system), Delivers 15 mg over 9 hours (1.6 mg/hr), Contains: 30 Patches in in a foil-sealed polypropylene tray, packed in a paper carton	NDC: 68968-5553-03	87818 Exp. 4/2021; 88274 Exp. 05/2021; 88531 Exp. 07/2021	Class II	Noven Pharmaceuticals Inc
Daytrana (methylphenidate transdermal system) Delivers 20 mg over 9 hours (2.2 mg/hr) Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton	NDC: 68968-5554-03	87580, 87819 Exp. 04/2021; 88244, 88245, 88532 Exp. 06/2021; 88533 Exp. 07/2021	Class II	Noven Pharmaceuticals Inc
Daytrana (methylphenidate transdermal system) Delivers 30 mg over 9 hours (3.3 mg/hr) Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton	NDC: 68968-5555-03	87377, 87572 Exp. 03/2021; 87581 Exp. 04/2021; 87820 Exp. 05/2021; 88246 Exp. 06/2021; 88535 Exp. 07/2021; 88536, 88537, 88939 Exp. 08/2021	Class II	Noven Pharmaceuticals Inc
Progesterone 200 mg Capsules	NDC: 43598-350-01	1399851P1 Exp. 02/2021	Class II	Dr. Reddy's Laboratories, Inc.



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Phenylephrine Hydrochloride 10 mg/mL Injection	NDC: 25021-0315-01	PHT8IB2, PHT9IB2 Exp. 08/2022; PHT1JB2 Exp. 09/2022	MW	Sagent Pharmaceuticals, Inc.
Telmisartan 20 mg Tablets	NDC: 62332-0087-30	190500566 Exp. 03/2022	MW	Alembic Pharmaceuticals, Inc.
Spironolactone 25 mg Tablets	NDC: 63629-1064-01; 63629-1064-02; 63629-1064-03	148969, 148791, 148991 Exp. 7/31/2022	Class I	Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals
Spironolactone 50 mg Tablets	NDC: 63629-1067-01	148992 Exp. 5/31/2022	Class II	Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals
Nortriptyline HCL 10 mg Capsules	NDC: 61919-0853-30	28DE2002 Exp. 10/31/2022	Class II	Direct Rx
Gabapentin 250 mg/5 mL Oral Solution, 5 mL per unit dose cup	NDC: 50383-311-07; 50383-0311-07	369409 Exp. 05/2021; 372393 Exp. 01/2022; 373112 Exp. 04/2022	Class II	Akorn, Inc.
Phenylephrine HCl 10 mg per mL Injection, 1 mL per Single-Dose Vial	NDC: 25021-0315-01	PHT8IB2, PHT9IB2 Exp. 08/2022; PHT1JB2 Exp. 09/2022	Class II	Sagent Pharmaceuticals Inc
Omeprazole Delayed-Release 20 mg Capsules	NDC: 51991-0643-10	191659 Exp. 05/2021	Class II	Breckenridge Pharmaceutical, Inc
Acyclovir Sodium 50 mg/mL Injection	NDC: 68382-0049-01; 68382-0048-01	L000155, L000156, L000126, L000127 Exp. 12/2021, 01/2021	MW	Zydus Pharmaceuticals Inc
Guanfacine 2 mg Extended-Release Tablets	NDC: 60505-3928-01	RX1662, RX1663, RX1664 Exp. 11/2022	MW	Apotex Corp.
0.9% Sodium Chloride Irrigation, 1000 mL Semi-Rigid Bottle	NDC: 00990-7138-09	16-808-4B, 16-803-4B, 16-809-4B Exp. 04/01/2023	Class II	ICU Medical Inc
Omeprazole 20 mg Delayed Release Capsules	NDC: 51407-0129-10	GS029673 Exp. 05/2021	Class II	Golden State Medical Supply 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:

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<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