

Drug Recall

DATE OF RECALL: April 27, 2023

DRUG NAME: Miscellaneous Products

RECALLING FIRM: Akorn Operating Company LLC.

REASON FOR RECALL: This recall was issued due to the closures and discontinuation of the Quality activities of these marketed products.

FDA LINK: N/A

OTHER DETAILS: N/A

RECALLED PRODUCT:

Drug Description	NDC 11
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383007916
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383033705
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383033706
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383033810
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383033811
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383033912
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383033913
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383034015
Acetaminophen & Codeine Phosphate Oral Solution 120mg & 12mg/5mL	50383034017
Acetic Acid Otic Solution	50383088915
Acyclovir Oral Suspension, 200mg/5mL	50383081016
Albuterol Sulfate Syrup, 2mg (base)	50383074016
Amantadine HCl Syrup, USP 50 mg per 5mL	50383080710
Amantadine HCl Syrup, USP 50 mg per 5mL	50383080712
Amantadine HCl Syrup, USP 50 mg per 5mL	50383080716
Apraclonidine Ophthalmic Solution 0.5%	17478071610
Apraclonidine Ophthalmic Solution 0.5%	17478071611
Artificial Tears	17478006235
Artificial Tears	13985060003
Artificial Tears	17478006012
Atropine Sulfate Ophthalmic Solution	17478021502
Atropine Sulfate Ophthalmic Solution	17478021505
Atropine Sulfate Ophthalmic Solution	17478021515
Atropine Sulfate Ophthalmic Solution	76478001502

Atropine Sulfate Ophthalmic Solution	76478001505
Atropine Sulfate Ophthalmic Solution	76478001515
Azelastine Hydrochloride Nasal Spray, 0.1%	50383094230
Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, 3.5g	17478023835
Calcipotriene Scalp Solution, 0.005%	50383073202
Calcitriol Injection 1 mcg and 2 mcg	17478093101
Calcitriol Injection 1 mcg and 2 mcg	17478093201
Cetrorelix Acetate for Injection, 0.25 mg/vial, Single-Dose Vial	17478079312
Cetrorelix Acetate for Injection, 0.25 mg/vial, Single-Dose Vial	17478079412
Cetrorelix Acetate for Injection, 0.25 mg/vial, Single-Dose Vial	17478079501
Ciclopirox Topical Solution 8%	50383041903
Ciclopirox Topical Solution 8%	50383041906
Cimetidine HCl Oral Solution	50383005008
Cimetidine HCl Oral Solution	50383096608
Clobetasol Propionate Cream 0.05%	50383026715
Clobetasol Propionate Cream 0.05%	50383026730
Clobetasol Propionate Cream 0.05%	50383026745
Clobetasol Propionate Cream 0.05%	50383026760
Clobetasol Propionate Cream 0.05%	50383026815
Clobetasol Propionate Cream 0.05%	50383026830
Clobetasol Propionate Cream 0.05%	50383026845
Clobetasol Propionate Cream 0.05%	50383026860
Clobetasol Propionate Ointment, 0.05%	50383026715
Clobetasol Propionate Ointment, 0.05%	50383026730
Clobetasol Propionate Ointment, 0.05%	50383026745
Clobetasol Propionate Ointment, 0.05%	50383026760
Clobetasol Propionate Ointment, 0.05%	50383026815
Clobetasol Propionate Ointment, 0.05%	50383026830
Clobetasol Propionate Ointment, 0.05%	50383026845
Clobetasol Propionate Ointment, 0.05%	50383026860
Clobetasol Propionate Shampoo, 0.05%	50383097904
Cromolyn Sodium Ophthalmic Solution 4%	17478029111
Detomidine Hydrochloride 20mL and 5mL	59399010505
Detomidine Hydrochloride 20mL and 5mL	59399010520
Dicyclomine Hydrochloride Injection USP, 20 mg/2 mL (10 mg/mL)	17478001502
Diuril® (chlorothiazide sodium) Injection	17478041940
DOCU LIQUID- docusate sodium liquid	50383034910
DOCU LIQUID- docusate sodium liquid	50383034911
DOCU LIQUID- docusate sodium liquid	50383077116
Ephedrine Injection 50 mg/mL	17478041501
Ephedrine Injection 50 mg/mL	17478041510
Ephedrine Injection 50 mg/mL	17478051701
Ephedrine Injection 50 mg/mL	17478095510
Ferrous Sulfate Elixir and Iron Supplement	50383062750



Fluticasone Propionate Nasal Spray	50383070009
Fluticasone Propionate Nasal Spray	50383070016
Gonak Hypromellose Ophth Sol	17478006412
Granisetron HCl Injection 1 mg/mL	17478054602
Granisetron HCl Injection 1 mg/mL	17478054605
Guaifenesin and Codeine Phosphate Liquid	50383008704
Guaifenesin and Codeine Phosphate Liquid	50383008705
Guaifenesin and Codeine Phosphate Liquid	50383008707
Guaifenesin and Codeine Phosphate Liquid	50383008710
Guaifenesin and Codeine Phosphate Liquid	50383008712
Guaifenesin and Codeine Phosphate Liquid	50383008716
Guaifenesin and Codeine Phosphate Liquid	50383006305
Guaifenesin and Codeine Phosphate Liquid	50383006306
Guaifenesin and Codeine Phosphate Liquid	50383006307
Guaifenesin and Codeine Phosphate Liquid	50383006310
Guaifenesin and Codeine Phosphate Liquid	50383006311
Guaifenesin and Codeine Phosphate Liquid	50383006312
Guaifenesin and Codeine Phosphate Liquid	50383006315
Guaifenesin and Codeine Phosphate Liquid	50383006317
Guaifenesin and Codeine Phosphate Liquid	50383006318
HydrALAZINE HCl Injection	17478093401
HydrALAZINE HCl Injection	17478093410
HydrALAZINE HCl Injection	17478093415
Hydrocortisone and Acetic Acid Otic Solution	50383090110
Hydromorphone High Potency Injection USP – Ampule and Vial	17478054001
Hydromorphone High Potency Injection USP – Ampule and Vial	17478054005
Hydromorphone High Potency Injection USP – Ampule and Vial	17478054050
IC-Green Sterile Indocyanine Green Injection USP	17478070102
Ketorolac Tromethamine Ophthalmic Solution, 0.5%	17478020910
Ketorolac Tromethamine Ophthalmic Solution, 0.5%	17478020911
Ketorolac Tromethamine Ophthalmic Solution, 0.5%	17478020919
Lactulose Syrup (Oral) and (Oral/Rectal)	50383079516
Lactulose Syrup (Oral) and (Oral/Rectal)	50383079564
Lactulose Syrup (Oral) and (Oral/Rectal)	50383035615
Lactulose Syrup (Oral) and (Oral/Rectal)	50383035617
Lactulose Syrup (Oral) and (Oral/Rectal)	50383035730
Lactulose Syrup (Oral) and (Oral/Rectal)	50383035731
Lactulose Syrup (Oral) and (Oral/Rectal)	50383035733
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077908
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077915
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077916
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077917
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077930
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077931



Lactulose Syrup (Oral) and (Oral/Rectal)	50383077932
Lactulose Syrup (Oral) and (Oral/Rectal)	50383077933
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024105
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024106
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024107
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024108
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024110
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024111
Levetiracetam Injection USP, 500 mg/5 mL (100 mg/mL) single-dose vial	50383024116
Levocarnitine Oral Solution, USP	50383017104
Levofloxacin Injection, 25 mg/mL	17478010720
Levofloxacin Injection, 25 mg/mL	17478010730
Levofloxacin Oral Solution	50383028604
Levofloxacin Oral Solution	50383028608
Levofloxacin Oral Solution	50383028610
Levofloxacin Oral Solution	50383028611
Levofloxacin Oral Solution	50383028616
Levofloxacin Oral Solution	50383028620
Levofloxacin Oral Solution	50383028621
Levofloxacin Opth Solution	17478010610
Lidocaine 2.5% & Prilocaine 2.5% Cream	50383066715
Lidocaine 2.5% & Prilocaine 2.5% Cream	50383066730
Lidocaine Ointment	50383034135
Lidocaine HCl Jelly USP, 2%	17478071110
Lidocaine HCl Jelly USP, 2%	17478071130
Lidocaine HCl Jelly USP, 2%	17478071131
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%	50383036315
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%	50383036317
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%	50383077504
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%	50383077515
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%	50383077517
Lorazepam Injection 2 mg/mL vial	17478004001
Lorazepam Oral Concentrate, 2mg	50383070530
Megestrol Acetate Oral Suspension 40 mg/mL	50383085910
Megestrol Acetate Oral Suspension 40 mg/mL	50383085911
Megestrol Acetate Oral Suspension 40 mg/mL	50383085912
Megestrol Acetate Oral Suspension 40 mg/mL	50383085920
Megestrol Acetate Oral Suspension 40 mg/mL	50383085921
Megestrol Acetate Oral Suspension 40 mg/mL	50383085922
Megestrol Acetate Oral Suspension 40 mg/mL	50383085924
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052302
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052305
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052310
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052325



Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052355
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052401
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052402
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052405
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052410
Midazolam Injection USP 1 mg/mL & 5 mg/mL - vial	17478052415
Moxifloxacin HCl Solution 0.5%	17478051919
Naloxone Injection 0.4 mg/mL; 1 mL and 10mL Vial	17478004101
Naloxone Injection 0.4 mg/mL; 1 mL and 10mL Vial	17478004210
Neomycin & Polymyxin B Sulfates & Bacitracin Zinc Ophthalmic Ointment	17478023535
Olopatadine HCl Nasal Spray, 665 mcg/spray	50383094323
Olopatadine Solution 0.1% and 0.2%	17478030805
Olopatadine Solution 0.1% and 0.2%	51407049905
Oxcarbazepine Oral Suspension USP, 300 mg/5 mL	50383031284
Pilocarpine 1, 2, & 4%	17478022312
Pilocarpine 1, 2, & 4%	17478022412
Pilocarpine 1, 2, & 4%	17478022612
Prednisolone Sodium Phosphate Oral Solution	50383004224
Prednisolone Sodium Phosphate Oral Solution	50383004248
Promethazine HCl & Codeine Phosphate Oral Solution	50383080416
Promethazine HCl & Codeine Phosphate Oral Solution	50383080404
Promethazine HCl Oral Solution	50383080104
Promethazine HCl Oral Solution	50383080108
Promethazine HCl Oral Solution	50383080116
Proparacaine HCl Ophthalmic Solution, 0.5%	17478026312
Rifampin Capsules USP, 150 mg	61748001511
Rifampin Capsules USP, 150 mg	61748001530
Rifampin Capsules USP, 300 mg	61748001801
Rifampin Capsules USP, 300 mg	61748001811
Rifampin Capsules USP, 300 mg	61748001830
Rifampin Capsules USP, 300 mg	61748001860
Ropivacaine Hydrochloride Injection USP, 0.2% and 5mg/mL	17478008130
Ropivacaine Hydrochloride Injection USP, 0.2% and 5mg/mL	17478008290
Ropivacaine Hydrochloride Injection USP, 0.2% and 5mg/mL	17478008292
Fentanyl Citrate Injection	17478003002
Fentanyl Citrate Injection	17478003005
Fentanyl Citrate Injection	17478003010
Fentanyl Citrate Injection	17478003020
Fentanyl Citrate Injection	17478003025
Fentanyl Citrate Injection	17478003055
Sodium Chloride Ophthalmic Ointment	17478062235
Sodium Chloride Solution Drops	17478062312
Sodium DIURIL	76478071140
Sufenta (Sufentanil Citrate Injection, USP) 50 mcg/mL	17478005001



Sufenta (Sufentanil Citrate Injection, USP) 50 mcg/mL	17478005002
Sufenta (Sufentanil Citrate Injection, USP) 50 mcg/mL	17478005005
Sulfamethoxazole & Trimethoprim Oral Suspension USP, 200mg/40mg per 5mL	50383082316
Sulfamethoxazole & Trimethoprim Oral Suspension USP, 200mg/40mg per 5mL	50383082416
Sulfamethoxazole & Trimethoprim Oral Suspension USP, 200mg/40mg per 5mL	50383082420
Sulfamethoxazole & Trimethoprim Oral Suspension USP, 200mg/40mg per 5mL	50383082421
Timolol Maleate Ophthalmic Solution 0.5%	17478028810
Timolol Maleate Ophthalmic Solution 0.5%	17478028811
Timolol Maleate Ophthalmic Solution 0.5%	17478028812
Timolol Maleate Ophthalmic Solution 0.5%	17478028825
Timolol Maleate Ophthalmic Solution 0.5%	17478028910
Timolol Maleate Ophthalmic Solution 0.5%	17478028911
Timolol Maleate Ophthalmic Solution 0.5%	17478028912
Timolol Maleate Ophthalmic Solution 0.5%	17478028925
Tobramycin Inhalation Solution USP, 300 mg/5 mL	17478034038
Tobramycin Ophthalmic Solution 0.3%	17478029010
Tobramycin Ophthalmic Solution 0.3%	17478029020
Trihexyphenidyl HCl Oral Sol	61748005416
Tropicamide Ophthalmic Solution 0.5% and 1%	17478010112
Tropicamide Ophthalmic Solution 0.5% and 1%	17478010212
Tropicamide Ophthalmic Solution 0.5% and 1%	17478010220
Valproic Acid Oral Solution	50383079205
Valproic Acid Oral Solution	50383079206
Valproic Acid Oral Solution	50383079207
Valproic Acid Oral Solution	50383079210
Valproic Acid Oral Solution	50383079212
Valproic Acid Oral Solution	50383079216
Vitamin D Suppl. Drops 50mL	50383091750
XOPENEX- levalbuterol hydrochloride solution, concentrate	17478017101
XOPENEX- levalbuterol hydrochloride solution, concentrate	17478017130

