COMPANY ANNOUNCEMENT

Premier Pharmacy Labs Issues Voluntary Nationwide Recall of all Unexpired Sterile Drug Product Lots Due to Lack of Sterility Assurance

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Read Announcement

View Product Photos

Summary

Company Announcement Date: June 18, 2019 FDA Publish Date: June 18, 2019 Reason for Announcement: Lack of Sterility Assurance Company Name: Premier Pharmacy Labs Inc Brand Name: Premier Pharmacy Labs Product Description: All Products Intended to be Sterile

Company Announcement

Premier Pharmacy Labs is voluntarily recalling all unexpired products, intended to be sterile, due to a lack of sterility assurance. The Unexpired Sterile Drug Product Lots (include dates dispensed) are being recalled due to concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination and lack of product specific process validations. The nationwide recall includes lots of sterile drug products to the consumer/user level. Premier Pharmacy Labs Issues Voluntary Nationwide Recall of all Unexpired Sterile Drug Product Lots Due to Lack of Sterility Assurance...

Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, Premier Pharmacy Labs has not received any reports of adverse events related to the products but is issuing this recall out of an abundance of caution following a commitment made during a recent inspection of the company's facility.

The scope of this recall is all commercially distributed product lots compounded in the Weeki Wachee, FL location currently within their labeled expiration date in response to an FDA concerns raised during the most recent inspection carried out from 29 April, 2019 to 12 June, 2019.

Premier Pharmacy Labs is notifying customers of the voluntary recall by certified letter. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per the hospital protocol. Customers with any of the affected medications can also reference Premier Pharmacy Labs Website at <u>https://premierpharmacylabs.com/ (https://premierpharmacylabs.com/)</u> <u>(http://www.fda.gov/about-fda/website-policies/website-disclaimer)</u> for more information on the specific lot numbers affected and contact information.

Patients and healthcare providers with questions regarding this recall can contact Premier Pharmacy Labs at 1-800-752-7139, Monday through Friday, between 8:30am and 5pm, Central Standard Time or via e-mail at <u>recalls@premierpharmacylabs.com</u> (mailto:recalls@premierpharmacylabs.com).

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)or call 1-800-332- 1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

6/19/2019

Premier Pharmacy Labs Issues Voluntary Nationwide Recall of all Unexpired Sterile Drug Product Lots Due to Lack of Sterility Assurance...

Ron Martin

1-800-752-7139

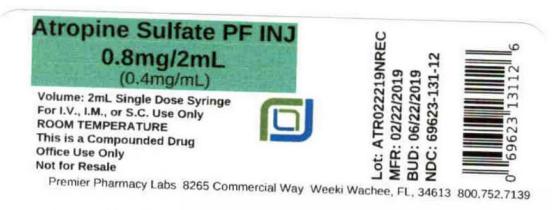
recalls@premierpharmacylabs.com (mailto:recalls@premierpharmacylabs.com)

Media:

Vern Allen

L 1-800-752-7139

Product Photos



Atropine Sulfate PF INJ 0.8mg/2mL

Office Use: Use as directed by a Health Care Professional.

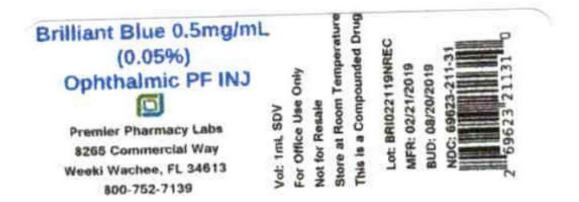
(0.4mg/mL)

ARMACY LAB

Each mL Contains: Atropine Sulfate 0.4mg, Sodium Chloride 0.9% INJ QS. May contain NaOH and/or Sulfuric Acid for pH adjustment

This is a Compounded Drug

8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



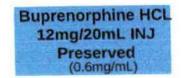
Brilliant Blue 0.5mg/mL (0.05%) PF Ophthalmic INJ

Office Use: Inject into the eye as directed by a health care professional



Each mL Contains: Brilliant Blue 0.5mg, Sodium Chloride 0.9% qs May contain NaOH and/or HCl for pH adjustment

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and -1-800-FDA-1088)





Premier Pharmacy Labs 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 CIII **DOUBLE STRENGTH** Vol: Sterile 20mL MDV Store at Room Temperature This is a Compounded Drug Not For Resale OFFICE USE ONLY



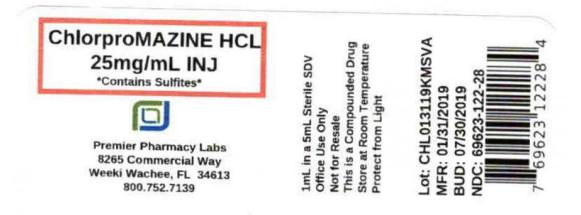
Buprenorphine HCL 12mg/20mL (0.6mg/mL) Injection

Office Use Only: Inject as Directed by a Health Care Professional



Each mL Contains: Buprenorphine HCL 0.6mg, Benzyl Alcohol 0.01 mL, Dextrose 5% Solution QS May Contain NaOH and/or HCl for pH adjustments

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Chlorpromazine 25 mg/mL INJ *Contains Sulfites*

Office Use: Use as directed by a health care professional.



Each mL contains: Chlorpromazine 25mg, Ascorbic Acid 2mg. Sodium bisulfite 1mg. Sodium chloride 6mg, Sodium sulfite 1mg, Sterile water for Injection QS, May Contain NaOH and/or HCI for pH adjusterments

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)

Dexamethasone Sodium Phosphate 24mg/m Preservative Free Sterile Solution for IN

Volume: 1mL Sterile Single-Use Syringe **Room Temperature** This is a Compounded Drug Office Use Only Not for Resale



Premier Pharmacy Labs 8265 Commercial Way Weeki Wachee, FL, 34613 800.752.7139



Dexamethasone Sodium Phosphate 24mg/mL Preservative Free Sterile Solution for INJ

Office Use: Inject as directed by a health care professional.



Each mL Contains: **Dexamethasone Sodium** Phosphate 33.1mg, Sodium Citrate Dihydrate 10mg, Sodium Hydroxide QS to pH Sterile Water for Inj QS to 1mL

This is a Compounded Drug

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A MAR HAND OF COMPACT PROPERTY AND A SUB-	operidol 0.625mg ctable Sterile Solu		1
Vol: 1mL in a 3mL Sterile S Room Temperature Protect from Light This is a Compounded Dru Office Use Only Not for Resale		Lot: DRO021919KMSEC MFR: 02/19/2019 BUD: 08/18/2019 NDC: 69623-185-10	0 69623 18510 5

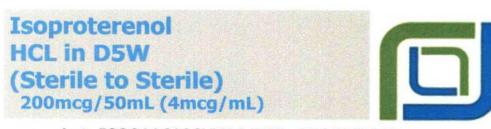
Droperidol 0.625mg/mL Injectable Solution

Office Use: Use as directed by a health care professional.



Each mL contains: Droperidol 0.625 mg, Lactic Acid qs for pH, Sterile Water for Injection qs. May Contain NaOH and/or HCI for pH adjustment

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



Lot: ISO011619SVVA1 BUD: 07/15/2019 MFR: 01/16/2019 Volume: 50mL

Each mL Contains: Isoproterenol 4mcg, Edetate Disodium 4mcg, Sodium Chloride 140mcg, Sodium Citrate (dihydrate) 41.4mcg, Citric Acid Anhydrous 50mcg, Dextrose 5%



Store at Room Temperature Protect from Light Sterile Single-Dose Bag This is a Compounded Drug Not For Resale- Office Use Only

Premier Pharmacy Labs 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139

Isoproterenol HCL 200mcg/50mL in D5W

Sterile-Sterile (4mcg/mL)

Office Use: Use as directed by a health care professional.



Each mL Contains: Isoproterenol HCL 4mcg, Edetate Disodium 4mcg, Sodium Chloride 140mcg, Sodium Citrate (dihydrate) 41.4mcg, Citric Acid Anhydrous 50mcg, Dextrose 5%, May Contain NaOH and/or HCl

This is a Compounded Drug

8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.com/medwatch and 1-800-FDA-1088)



Lot: ISO032519SVEC1 BUD: 09/21/2019 MFR: 03/25/2019 Volume: 50mL

Each mL Contains: Isoproterenol HCL 4mcg, Edetate Disodium 4mcg, Sodium Chloride 140mcg, Sodium Citrate (dihydrate) 41.4mcg, Citric Acid Anhydrous 50mcg, Sterile Water for INJ, Dextrose 5% QS



Store at Room Temperature Protect from Light Sterile Single-Dose Bag This is a Compounded Drug Not For Resale- Office Use Only

Premier Pharmacy Labs 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139

Isoproterenol HCL 200mcg/50mL in D5W Non Sterile to Sterile

(4mcg/mL)

Office Use: Use as directed by a health care professional.



HCL 4mcg, Edetate Disodium 4mcg, Sodium Chloride 140mcg, Sodium Citrate (dihydrate) 41.4mcg, Citric Acid Anhydrous 50mcg, Sterile Water for INJ, Dextrose 5% QS. May Contain NaOH and/or

HCI for pH adjustment

This is a Compounded Drug

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In case of an adverse event you may report to (www.fda.com/medwatch and 1-800-FDA-1088)



Lot: ISO022219SVEC1 BUD: 08/21/2019 MFR: 02/22/2019 Volume: 50mL

Each mL Contains: Isoproterenol 10mcg, Edetate Disodium 10mcg, Sodium Chloride 350mcg, Sodium Citrate (dihydrate) 103.5mcg, Citric Acid Anhydrous 125mcg, Sterile Water for INJ, Dextrose 5% QS



Store at Room Temperature Protect from Light Sterile Single-Dose Bag This is a Compounded Drug 3 Not For Resale- Office Use Only

Premier Pharmacy Labs 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139

Isoproterenol HCL 500mcg/50mL in D5W

(10mcg/mL)

Office Use: Use as directed by a health care professional.



Each mL Contains: Isoproterenol 10mcg, Edetate Disodium 10mcg, Sodium Chloride 350mcg, Sodium Citrate (dihydrate) 103.5mcg, Citric Acid Anhydrous 125mcg, Sterile Water for INJ, Dextrose 5% QS. May Contain NaOH and/or HCI for pH adjustment

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.com/medwatch and 1-800-FDA-1088)

Lidocaine 0.5% / is a Compounded Drug Store at Room Temperature .ot: LPH040319KMSEC Phenylephrine 0.75% ol: 1mL Sterile SDV P.F. INJ AFR: 04/03/2019 JD: 09/30/2019 69623-17 Office Use Only for Resale Premier Pharmacy Labs 8265 Commercial Way, Weeki Wachee FL, 34614 1 800.752.7139

Lidocaine 0.5% (5mg/mL) Phenylephrine 0.75% (7.5mg/mL)

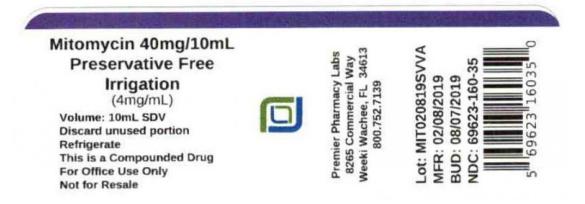
PF INJ

Office Use: Inject into the eye as directed by a health care professional.



Each mL Contains: Lidocaine HCL 5mg, Phenylephrine 7.5mg, Sterile water qs May contain NaOH and/or HCl for pH adjustment

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



Mitomycin 40mg/10mL Preservative Free Irrigation (4mg/mL)

Office Use:

This medication is given by irrigation into the bladder by a health care professional. Dilute with Sterile Water.



Each mL contains: Mitomycin 4mg, Propylene Glycol 0.6mL, Sterile Water for Irrigation QS May contain NaOH and/or HCI for pH adjustment

This is a compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



Premier Pharmacy Labs 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 Vol: Sterile 50mL MDV Office Use Only Not for Resale This is a Compounded Drug Store at Room Temperature



Naloxone HCL Preserved INJ 500mg/50mL (10mg/mL)

Office Use: Inject as directed by a health care professional.



Each mL contains: Naloxone 10mg Benzyl Alchohol 0.01mL Sterile Water for Injection QS, May Contain NaOH and/or HCI for pH adjustment

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Neostigmine Methylsulfate 5mg/5mL (1mg/mL)

Office Use: Inject as directed by a health care professional.



Each mL Contains: Neostigmine Methylsulfate 0.0011g Methylparaben 0.0018g Propylparaben 0.0002g Sterile Water for Injection QS May contain NaOH and/or HCI for pH adjustment

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



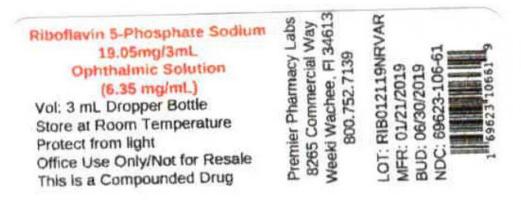
Office Use: Use as directed by a Healthcare Professional

Contains Sulfites



es* Each mL Contains: Phenylephrine 100mcg, Sodium Citrate(Dihydrate) 40mcg, Citric Acid(Anhydrous) 10mcg, Sodium Metabisulfite 20mcg, Sodium Chloride 0.9% QS, May Contain NaOH and/or HCI for pH adjustment

This is a Compounded Drug for pH adjustment 8269 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



Riboflavin 5-Phosphate Sodium 19.05mg/3mL **Ophthalmic Solution** (6.35mg/mL)

Office Use: Instill into eye as directed by a health care professional

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Each mL Contains: Riboflavin 5-Phosphate Sodium Dihydrate 6.88mg, Sodium Iodide USP 0.015mg, Sterile Water for Injection, Sodium Chloride Injection 0.9% QS, pH adjusted with Sodium Hydroxide

This is a Compounded Drug

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Sodium Bicarbonate INJ 8.4% 50 mEq/50mL (84mg/mL) (1mEg/mL)

Office Use: Use as directed by a health care professional



Each mL contains: Sodium Bicarbonate 84 mg. Sterile Water Injection QS

This is a Compounded Drug

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In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



Succinylcholine Chloride 100mg/5mL (20mg/mL)

Office Use: Inject as directed by a health care professional.



Each mL Contains: Succinylcholine Chloride Dihydrate 20mg, Methylparaben 1mg. Sodium Chloride 4.5mg, Sterile Water QS, May contain NaOH and/or HCI for pH adjustment

This is a Compounded Drug

8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)



Succinylcholine Chloride 200mg/10mL (20mg/mL) Each mL Contail

Office Use: Inject as directed by a health care professional.



Each mL Contains: Succinylcholine Chloride Dihydrate 20mg, Methylparaben 1mg, Sodium Chloride 4.5mg, Sterile Water QS, May contain NaOH and/or HCl for pH adjustment

This is a Compounded Drug 8265 Commercial Way Weeki Wachee, FL 34613 800.752.7139 In case of an adverse event you may report to (www.fda.gov/medwatch and 1-800-FDA-1088)

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