

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.

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 <https://premierpharmacylabs.com/> (<https://premierpharmacylabs.com/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) 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 recalls@premierpharmacylabs.com (<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:

Ron Martin

☎ 1-800-752-7139

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

Media:


Vern Allen

☎ 1-800-752-7139


Product Photos

Atropine Sulfate PF INJ
0.8mg/2mL
 (0.4mg/mL)

Volume: 2mL Single Dose Syringe
 For I.V., I.M., or S.C. Use Only
 ROOM TEMPERATURE
 This is a Compounded Drug
 Office Use Only
 Not for Resale



Lot: ATR022219NREC
 MFR: 02/22/2019
 BUD: 06/22/2019
 NDC: 69623-131-12



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

Atropine Sulfate PF INJ
0.8mg/2mL
(0.4mg/mL)


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



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%)
Ophthalmic PF INJ



Premier Pharmacy Labs
 8265 Commercial Way
 Weeki Wachee, FL 34613
 800-752-7139

Vol: 1mL SDV
 For Office Use Only
 Not for Resale
 Store at Room Temperature
 This is a Compounded Drug

Lot: BRI022119NREC
 MFR: 02/21/2019
 BUD: 08/20/2019
 NDC: 69623-211-31



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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)

Buprenorphine HCL
12mg/20mL INJ
Preserved
(0.6mg/mL)



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

LOT: BUP030819NRVA
MFR: 03/08/2019
BUD: 08/31/2019
NDC: 69623-703-37

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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

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)

ChlorproMAZINE HCL
25mg/mL INJ
Contains Sulfites



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

1mL in a 5mL Sterile SDV
Office Use Only
Not for Resale
This is a Compounded Drug
Store at Room Temperature
Protect from Light

Lot: CHL013119KMSVA
MFR: 01/31/2019
BUD: 07/30/2019
NDC: 69623-122-28

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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 HCl
for pH adjustments

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/mL Preservative Free Sterile Solution for INJ

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

Lot: DEX020119NRVA
MFR: 02/01/2019
BUD: 07/01/2019
NDC: 69623-252-10



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
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)

Droperidol 0.625mg/mL Injectable Sterile Solution

Vol: 1mL in a 3mL Sterile Single-Use Syringe
Room Temperature
Protect from Light
This is a Compounded Drug
Office Use Only
Not for Resale



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

Lot: DRO021919KMSEC
MFR: 02/19/2019
BUD: 08/18/2019
NDC: 69623-185-10



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 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)

**Isoproterenol
HCL in D5W
(Sterile to Sterile)
200mcg/50mL (4mcg/mL)**



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%

NDC: 69623-230-57



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
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)

Isoproterenol HCL in D5W

200mcg/50mL (4mcg/mL)



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

NDC: 69623-240-57



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

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

(4mcg/mL)



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. 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.com/medwatch and 1-800-FDA-1088)

Isoproterenol HCL in D5W

500mcg/50mL (10mcg/mL)



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
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 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.com/medwatch and 1-800-FDA-1088)

**Lidocaine 0.5% /
Phenylephrine 0.75%**
P.F. INJ



Premier Pharmacy Labs
8265 Commercial Way,
Weeki Wachee FL, 34614
800.752.7139

Vol: 1mL Sterile SDV
This is a Compounded Drug
Store at Room Temperature
Office Use Only
Not for Resale

Lot: LPH040319KMSEC
MFR: 04/03/2019
BUD: 09/30/2019
NDC: 69623-176-31



**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)**

Volume: 10mL SDV
Discard unused portion
Refrigerate
This is a Compounded Drug
For Office Use Only
Not for Resale



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

Lot: MIT020819SVVA
MFR: 02/08/2019
BUD: 08/07/2019
NDC: 69623-160-35



**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 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)

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



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

LOT: NAL030419MMEC
MFR: 03/04/2019
BUD: 07/02/2019
NDC: 69623-235-39



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

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



Each mL contains:
Naloxone 10mg
Benzyl Alcohol 0.01mL
Sterile Water for Injection 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)

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

Vol: 5mL Single Dose Syringe
Store at Room Temperature
Protect from Light
For Slow I.V. Use
Hospital/Office Use Only
This is a Compounded Drug
Not for Resale

LOT: NEO032819NREC1
MFR: 03/28/2019
BUD: 09/24/2019
NDC: 69623-234-15

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NEOSTIGMINE 1:1,000
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Premier Pharmacy Labs
8265 Commercial Way
Weeki Wachee, FL 34613
800.752.7139

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
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)

**Orphenadrine Citrate 30mg/mL
Sterile Injectable Solution *Contains Sulfites***

Vol: 1mL Sterile Single-Use Syringe
Room Temperature
Protect from Light
This is a Compounded Drug
Office Use Only
Not for Resale



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

Lot: ORP031119KMSECA
MFR: 03/11/2019
BUD: 09/07/2019
NDC: 69623-104-10



Orphenadrine Citrate 30mg/mL Injectable Solution

Contains Sulfites

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



Each mL contains:
Orphenadrine Citrate 30 mg,
Sodium Metabisulfite 1mg,
Sodium Chloride 2.9 mg,
Sterile Water for Injection qs,
May Contain NaOH and/or HCl
for pH adjustments

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)

**PHENYLEphrine HCL PF INJ
in 0.9% Sodium Chloride**

1000mcg/10mL

Contains Sulfites
(100mcg/mL)

Vol: 10mL Single-Dose Syringe
Room Temperature
Protect from Light
This is a Compounded Drug
Hospital/Office Use Only
Not for Resale
RX Only



LOT: PHE022019NREC
MFR: 02/20/2019
BUD: 06/20/2019
NDC: 69623-236-16



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

**PHENYLEphrine HCL in Sodium Chloride 0.9% 1000mcg/10mL
(100mcg/mL)**

Contains Sulfites

Office Use:
Use as directed
by a Healthcare
Professional



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 HCl
for pH adjustment

This is a Compounded Drug

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
(6.35 mg/mL)**

Vol: 3 mL Dropper Bottle
Store at Room Temperature
Protect from light
Office Use Only/Not for Resale
This is a Compounded Drug

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

LOT: RIB012119NRVAR
MFR: 01/21/2019
BUD: 06/30/2019
NDC: 69623-106-61



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

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



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

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)

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

Volume: 50mL Sterile SDV
Store at Room Temperature
This is a Compounded Drug
For Hospital/Office Use Only
Not for Resale



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

LOT: SOD022119JEC
MFR: 02/21/2019
BUD: 08/20/2019
NDC: 69623-232-39



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

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
100mg/5mL
 (20mg/mL)

**WARNING:
 PARALYTIC
 AGENT**

Volume: 5mL
 Store at Room Temperature
 Protect from Light,
 Sterile Single-Use Syringe
 Hospital/Office Use Only
 This is a Compounded Drug
 Not For Resale

LOT: SUC032619IJEC
MFR: 03/26/2019
BUD: 08/23/2019
NDC: 69623-239-15



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**SUCCINYLcholine Chloride
 100mg/5mL (20mg/mL)
 5mL Syringe**

Premier
 8265 Commercial Way
 Weeki Wachee, FL 34613
 800.752.7139

Premier Pharmacy Labs

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
 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)

SUCCINYLcholine Chloride
200mg/10mL
 (20mg/mL)

**WARNING:
 PARALYTIC
 AGENT**

Vol: 10mL Sterile Single Dose Syringe
 Store at Room Temperature
 Protect from Light
 Sterile Single-Use Syringe
 Hospital/Office Use Only
 This is a Compounded Drug
 Not For Resale

LOT: SUC022819SVEC
BUD: 07/28/2019
MFR: 02/28/2019
NDC: 69623-239-16



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**SUCCINYLcholine Chloride
 200mg/10mL (20mg/mL)
 10mL Syringe**

Premier
 8265 Commercial Way
 Weeki Wachee FL 34613
 800.752.7139

Premier Pharmacy Labs

Succinylcholine Chloride 200mg/10mL (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
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)

➡ More Recalls, Market
Withdrawals, &
Safety Alerts (</safety/recalls>)

