

Company Announcement

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.

PharMEDium Services Issues Voluntary Nationwide Recall of Specific Lots of Potassium Phosphate and Succinylcholine Chloride Due to a Lack of Sterility Assurance

For Immediate Release

June 26, 2017

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Announcement

[View Product Photos](#)

PharMEDium Services is conducting a limited, voluntary recall due to Hospira Inc.'s ("Hospira") June 15, 2017 recall announcement that microbial growth was detected during a routine simulation of the manufacturing process and therefore there was a lack of sterility assurance. The products being recalled by PharMEDium Services were compounded using certain Hospira products. The recalled products are specific lots of Potassium Phosphate and Succinylcholine Chloride. This is a secondary recall based on a Hospira's recent recall:

<https://www.fda.gov/Safety/Recalls/ucm563383.htm> ([/Safety/Recalls/ucm563383.htm](https://www.fda.gov/Safety/Recalls/ucm563383.htm)).

Per Hospira, in the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated.

To date, PharMEDium Services has not received any reports of product complaints and/or adverse events related to the products.

These products were not distributed directly to patients or consumers, but rather to healthcare facilities (e.g. hospitals) in the United States.

The recalled lots are as follows:

Product	Strength	Lot Number	Expiration Date	NDC Number
2K5281	10 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 250 mL in 250 mL Intravia Bag	171280011S	8/7/2017	61553-281-11
2K5282	15 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 250 mL in 250 mL Intravia Bag	171530101S	9/3/2017	61553-282-11
		171230071D	8/2/2017	61553-282-11
		171170014S	7/27/2017	61553-282-11
		171210127S	7/31/2017	61553-282-11
		171240191S	8/3/2017	61553-282-11
		171320190S	8/13/2017	61553-282-11
		171570058D	9/5/2017	61553-282-11
		171240002D	8/3/2017	61553-282-11
		171240004D	8/3/2017	61553-282-11
		171280041D	8/7/2017	61553-282-11
		171290077D	8/8/2017	61553-282-11
		171300076D	8/9/2017	61553-282-11
		171310058D	8/10/2017	61553-282-11
		171320059D	8/13/2017	61553-282-11
		171360062D	8/15/2017	61553-282-11
		171360068D	8/15/2017	61553-282-11
171380076D	8/17/2017	61553-282-11		
171390064D	8/20/2017	61553-282-11		
171390065D	8/20/2017	61553-282-11		
171500064D	8/29/2017	61553-282-11		
2K5283	30 mMol Potassium Phosphate (Preservative Free) in 5% Dextrose 500 mL in 500 mL Intravia Bag	171350099S	8/14/2017	61553-283-03

Product	Strength	Lot Number	Expiration Date	NDC Number
2K5284	7 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	171220061D	8/1/2017	61553-284-48
		171430008D	8/22/2017	61553-284-48
		171450015D	8/24/2017	61553-284-48
		171510062D	8/30/2017	61553-284-48
		171250023D	8/6/2017	61553-284-48
2K5285	30 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 500 mL in 500 mL Intravia Bag	171240007S	8/3/2017	61553-285-03
		171280055D	8/7/2017	61553-285-03
		171370011S	8/16/2017	61553-285-03
		171360005S	8/14/2017	61553-285-03
		171320008S	8/13/2017	61553-285-03
		171380086D	8/17/2017	61553-285-03
		171500071D	8/29/2017	61553-285-03
		171280055D	8/7/2017	61553-285-03
171320003D	8/10/2017	61553-285-03		
2K5286	9 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	171520062D	8/31/2017	61553-286-48
2K5287	20 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	171320001D	8/10/2017	61553-287-48
2K5288	10 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	171290006S	8/7/2017	61553-288-48
		171280125S	8/7/2017	61553-288-48
		171280006S	8/6/2017	61553-288-48
		171360002S	8/15/2017	61553-288-48
		171290028D	8/8/2017	61553-288-48
2K5290	30 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 250 mL in 250 mL Intravia Bag	171180027S	7/29/2017	61553-290-11
		171230013S	8/2/2017	61553-290-11
		171360008S	8/14/2017	61553-290-11
		171560025D	9/4/2017	61553-290-11
		171360019D	8/15/2017	61553-290-11
		171220058D	8/1/2017	61553-290-11
		171380085D	8/17/2017	61553-290-11
		171430069D	8/22/2017	61553-290-11
2K5291	15 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 250 mL in 250 mL Intravia Bag with Additive Cap	171210005S	7/30/2017	61553-291-11
		171500072D	8/29/2017	61553-291-11
		171230008D	8/2/2017	61553-291-11
		171560028D	9/4/2017	61553-291-11
2K5292	15 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 150 mL in 150 mL Intravia Bag	171370005S	8/15/2017	61553-292-01
		171450012D	8/24/2017	61553-292-01
		171510059D	8/30/2017	61553-292-01
		171440016D	8/23/2017	61553-292-01
		171280054D	8/7/2017	61553-292-01
		171560027D	9/4/2017	61553-292-01
		171320002D	8/10/2017	61553-292-01

Product	Strength	Lot Number	Expiration Date	NDC Number
2K5295	15 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	171320006S	8/13/2017	61553-295-48
		171320014D	8/13/2017	61553-295-48
		171360020D	8/15/2017	61553-295-48
		171520063D	8/31/2017	61553-295-48
2K5298	7.5 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	171320109S	8/13/2017	61553-298-48
		171210102S	7/31/2017	61553-298-48
		171560012S	9/4/2017	61553-298-48
2K5299	7.5 mMol Potassium Phosphate (Preservative Free) in 5% Dextrose 100 mL in 150 mL Intravia Bag	171450017D	8/24/2017	61553-299-48
2K5300	15 mMo1 Potassium Phosphate (Preservative Free) in 5% Dextrose	171420030D	8/21/2017	61553-300-11
2K5301	40 mMol Potassium Phosphate (Preservative Free) in 0.9% Sodium Chloride 250 mL in 250 mL Intravia Bag	171220007S	7/31/2017	61553-364-65
		171280129S	8/7/2017	61553-364-65
		171320112S	8/13/2017	61553-364-65
		171590010S	9/7/2017	61553-364-65
2K5310	9 mMol Potassium Phosphate (Preservative Free) in 5% Dextrose 50 mL in 50 mL Intravia Bag	171560007S	9/4/2017	61553-310-41
		171160002S	7/26/2017	61553-310-41
3364NO	20 mg/mL Succinylcholine Chloride Injection (Preserved) 10 mL in 10 mL BD Syringe	171450001D	8/23/2017	61553-364-65
		171450002D	8/23/2017	61553-364-65
		171450056D	8/24/2017	61553-364-65
		171440058D	8/23/2017	61553-364-65
		171390027D	8/20/2017	61553-364-65
		171390026D	8/20/2017	61553-364-65
		171430062D	8/22/2017	61553-364-65
		171420074D	8/21/2017	61553-364-65
		171370064D	8/16/2017	61553-364-65

PharMEDium Services is committed to product quality and patient safety in all instances and is therefore issuing this recall.

PharMEDium Services is notifying customers of the voluntary recall by phone. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website for more information on the specific lot numbers affected and contact information: www.pharmedium.com (www.pharmedium.com).

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at (847) 457-2220, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at shasan@pharmedium.com (<mailto:shasan@pharmedium.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.

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Product Photos

NDC# 61553-281-11

Service Code 2K5281

Potassium PHOSphate

in 0.9% Sodium Chloride

10 mMol 250 mL Bag

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 250.00 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



(01)000155(20)1111

Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-282-11

Service Code 2K5282

Potassium PHOSphate

in 0.9% Sodium Chloride

15 mMol 250 mL Bag

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 250.00 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



(01)000155(20)1111

Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553 – 283 – 03

Service Code 2K5283

Potassium PHOSphate

in 5% Dextrose

30 mMol 500 mL Bag

Lot# MB1740001L

Expiration Date 01 – 01 – 1900

Total Volume 500.00 mL

Injection



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
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Sugar Land, TX 77478 800 – 523 – 7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553 – 284 – 48

Service Code 2K5284

Potassium PHOSphate

in 0.9% Sodium Chloride

7 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01 – 01 – 1900

Total Volume 100 mL

Injection



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800 – 523 – 7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-286-48

Service Code 2K5286

Potassium PHOSphate

in 0.9% Sodium Chloride

9 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 100 mL

Injection



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-287-48

Service Code 2K5287

Potassium PHOSphate

in 0.9% Sodium Chloride

20 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 100 mL

Injection



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
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Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553 – 288 – 48

Service Code 2K5288

Potassium PHOSphate

in 0.9% Sodium Chloride

10 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01 – 01 – 1900

Total Volume 100 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800 – 523 – 7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553 – 290 – 11

Service Code 2K5290

Potassium PHOSphate

in 0.9% Sodium Chloride

30 mMol 250 mL Bag

Lot# MB1740001L

Expiration Date 01 – 01 – 1900

Total Volume 250.00 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800 – 523 – 7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-291-11

Service Code 2K5291

Potassium PHOSphate

in 0.9% Sodium Chloride

15 mMol 250 mL Bag

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 250.00 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



Potassium
PHOSphate

Use as Directed, Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-292-01

Service Code 2K5292

Potassium PHOSphate

in 0.9% Sodium Chloride

15 mMol 150 mL Bag

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 150.00 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



Potassium
PHOSphate

Use as Directed, Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
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This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553 – 295 – 48

Service Code 2K5295

Potassium PHOSphate

in 0.9% Sodium Chloride

15 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01 – 01 – 1900

Total Volume 100 mL

Injection



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800 – 523 – 7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553 – 298 – 48

Service Code 2K5298

Potassium PHOSphate

in 0.9% Sodium Chloride

7.5 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01 – 01 – 1900

Total Volume 100 mL

Injection



Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800 – 523 – 7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-299-48

Service Code 2K5299

Potassium PHOSphate

in 5% Dextrose

7.5 mMol in 100 mL

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 100 mL

Injection



Potassium
PHOSphate

Use as Directed, Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-300-11

Service Code 2K5300

Potassium PHOSphate

in 5% Dextrose

15 mMol in 250 mL

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 250.00 mL

Injection



Potassium
PHOSphate

Use as directed, Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-301-11

Service Code 2K5301

Potassium PHOSphate

in 0.9% Sodium Chloride

40 mMol in 250 mL

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 250.00 mL

Injection



Use as Directed, Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-310-41

Service Code 2K5310

Potassium PHOSphate

in 5% Dextrose

9 mMol in 50 mL

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 50.00 mL

Injection



Use as Directed, Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

NDC# 61553-285-03

Service Code 2K5285

Potassium PHOSphate

in 0.9% Sodium Chloride

30 mMol 500 mL Bag

Lot# MB1740001L

Expiration Date 01-01-1900

Total Volume 500.00 mL

Injection

(17)000101(10)MB1740001L(21)XXXX



(01)000105(2)0001

Use as Directed. Rx Only.
Store at Room Temperature. Protect from Freezing.

PharMEDium Services, LLC
12620 W. Airport Blvd #130
Sugar Land, TX 77478 800-523-7749



Potassium
PHOSphate

This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.

succinylcholine Chloride

20 mg per mL
200 mg per 10 mL

10 mL Total Volume
For IV Use

2R3304
ROOM TEMP STORAGE

Injection

Exp 01-01-1900

NDC# 61553-364-05

Lot# MB1740001L

PharMEDium Services, LLC 2124 South Ave Cleveland, MO 64601-2104

US Pat 5582200

WARNING: Paralyzing Agent

Compounded Drug. Not for Resale.
Hospital/Office Use Only.

succinylcholine succinylcholine succinylcholine succinylcholine

succinylcholine succinylcholine succinylcholine succinylcholine

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