

## COMPANY ANNOUNCEMENT

# PharMEDium Services, LLC Issues Voluntary Nationwide Recall of 0.5 mg/mL HYDRomorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe Due to Presence of Sulfite

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.

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## Summary

**Company Announcement Date:**

June 28, 2019

**FDA Publish Date:**

June 28, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

The electronic customer ordering system stated it is sulfite-free, but the product contains sulfite.

**Company Name:**

PharMEDium Services, LLC

**Brand Name:**

PharMEDium

**Product Description:**

0.5 mg/mL HYDRomorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe

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## Company Announcement

PharMEDium Services, LLC is voluntarily recalling 45 lots of 0.5 mg/mL HYDRomorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe to the user level. The product is being recalled because PharMEDium's electronic customer ordering system stated it is sulfite-free, but the product contains sulfite.

**Risk Statement:**

Serious adverse reactions could occur in patients with a sulfite allergy who are exposed to Hydromorphone containing sulfites. The reactions may range from mild wheezing to severe bronchospasm and anaphylaxis. To date, PharMEDium Services, LLC has not received any adverse event reports related to sulfite reactions or sensitivity.

The product is used for relief of moderate to severe pain in opioid tolerant patients and is packaged as 1 mL in 3 mL BD Syringe, in packages of 5 syringes, NDC # 61553-352-78. 28,140 syringes were distributed to a total of 6 customers in the USA. The complete list of affected HYDROmorphone HCl is included in the table below which contains the product description, lot number, expiration date and NDC.

Service Code	Service Code Description	Lot Number	Expiration Date	NDC
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190670030D	06/09/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190670031D	06/09/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190670032D	06/09/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190670033D	06/09/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190710015D	06/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190710016D	06/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190710017D	06/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190710018D	06/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190710019D	06/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190730028D	06/13/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190730029D	06/13/2019	61553-352-78

<b>Service Code</b>	<b>Service Code Description</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b>NDC</b>
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190730030D	06/13/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190740018D	06/16/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190770028D	06/17/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190770029D	06/17/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190780027D	06/18/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190780028D	06/18/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190780029D	06/18/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190790030D	06/19/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190800012D	06/20/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190800013D	06/20/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190800015D	06/20/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190800016D	06/20/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190810033D	06/23/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190810034D	06/23/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190810035D	06/23/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190810036D	06/23/2019	61553-352-78

Service Code	Service Code Description	Lot Number	Expiration Date	NDC
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190840002D	06/24/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190870008D	06/27/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190910015D	07/01/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190980033D	07/08/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190990017D	07/09/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190990030D	07/09/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191000035D	07/10/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191010008D	07/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9%	191010009D	07/11/2019	61553-352-78
	Sodium Chloride 1 mL in 3 mL BD Syringe			
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191010010D	07/11/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191050002D	07/15/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191120002D	07/22/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191160001D	07/28/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	190800014D	06/20/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191210020D	07/31/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191210021D	07/31/2019	61553-352-78

Service Code	Service Code Description	Lot Number	Expiration Date	NDC
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191210022D	07/31/2019	61553-352-78
2R3352-5	0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe	191220017D	08/01/2019	61553-352-78

The product can be identified by referring to the sample label included with this release.

PharMEDium Services, LLC has notified all six customers by email/phone and has arranged for replacement orders of all recalled products. All six customers have been advised to identify, quarantine and destroy any remaining product according to their facilities policies and procedures and to notify PharMEDium Services, LLC of the units requiring credit. Customers have been notified to 100% effectiveness and all six customers have responded with the number of syringes for credit. They have been instructed on how to receive replacement orders.

Consumers with questions regarding this recall can contact PharMEDium Services, LLC by dialing 800-523- 7749 (8:00 am – 5:00 pm Central Time) or [Quality1@pharmedium.com](mailto:Quality1@pharmedium.com) (<mailto:Quality1@pharmedium.com>) by email. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 \(/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda\)](/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: [Download form \(/safety/medical-product-safety-information/forms-reporting-fda\)](/safety/medical-product-safety-information/forms-reporting-fda) 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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## Company Contact Information

### Consumers:

PharMEDium Services, LLC

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✉ [Quality1@pharmedium.com](mailto:Quality1@pharmedium.com) (<mailto:Quality1@pharmedium.com>)

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