Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-062-CG
July 1st, 2022

FDA announced that, Bryant Ranch Prepack Inc. is voluntarily recalling one lot of Morphine Sulfate 30 mg Extended-Release tablets (Comprised of 10 bottles), and one lot of Morphine Sulfate 60 mg Extended-Release tablets (Comprised of 10 bottles) to the consumer level listed in the table below. The products have been found to have incorrect labeling where bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets

RECOMMENDATIONS

1. Bryant Ranch Prepack is notifying its distributors and customers by email, phone, and letter, and is arranging for return of all recalled products.

2. Consumers/distributors/retailers that have these products which are being recalled should stop using and contact Bryant Ranch Prepack Inc. at: cs@brppharma.com or call 877-885-0882.

3. Consumers with questions regarding this recall can contact Bryant Ranch Prepack Inc. by 877-885-0882 or cs@brppharma.com, Monday-Friday 7:30am-5:00pm PDT. 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.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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Bryant Ranch Prepack Inc. Issues Voluntary Nationwide Recall of Morphine Sulfate 30 mg Extended Release and Morphine Sulfate 60 mg Extended-Release Due to Label-Mix Up

Summary:

Company Announcement Date: June 28, 2022
FDA Publish Date: June 29, 2022
Product Type: Drugs
Reason for Announcement: Incorrect labeling
Company Name: Bryant Ranch Prepack Inc.
Brand Name: Bryant Ranch Prepack Inc.
Product Description: Morphine Sulfate 30 mg Extended-Release tablets

Company Announcement

06/28/2022 – Burbank, California, Bryant Ranch Prepack Inc. is voluntarily recalling one lot of Morphine Sulfate 30 mg Extended-Release tablets (Comprised of 10 bottles), and one lot of Morphine Sulfate 60 mg Extended-Release tablets (Comprised of 10 bottles) to the consumer level listed in the table below. The products have been found to have incorrect labeling where bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.

Risk Statement: Patients prescribed the 30 mg dose who receive the 60 mg dose could be at risk for overdose and death. Patients prescribed the 60 mg dose who receive the 30 mg dose may experience withdrawal and untreated pain if the dose given is too low. To date, Bryant Ranch Prepack Inc. has not received any reports of adverse events related to this recall.

Product	Strength	Quantity per bottle	NDC	Lot	Expiration
Morphine Sulfate Extended-Release Tablets	30 mg	100	63629-1088-01	179642	11/30/2023
	60 mg	100	63629-1089-01	179643	08/31/2023

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Morphine Sulfate Extended-Release tablets are used to manage severe pain. The 30 mg tablets are round, purple-colored, film-coated tablets debossed with "RD" and "71" on one side and plain on the other side. The 60 mg tablets are round, light orange-colored, film-coated tablets debossed with "RD" and "72" on one side and plain on the other side.

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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
- Regular Mail or Fax: Download form 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

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