

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

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Bryant Ranch Prepack has posted a lot recall of Morphine Sulfate 30 mg and 60 mg Extended-Release tablets.

About this recall:

Bryant Ranch Prepack. 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. Bottles labeled Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.

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

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found below.

What this means to you:

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.

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.

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

Consumers with questions regarding this recall can contact Bryant Ranch Prepack Inc. at 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.

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: <u>Download form</u> 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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bryant-ranch-prepack-incissues-voluntary-nationwide-recall-morphine-sulfate-30-mg-extended-release

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.

