COMMUNICATION

COM-2022-038

30
JUNE
2022

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

06/29/2022

Drug Information:

National Drug Code

63629-1088-01, 63629-1089-01

Product Description

Morphine sulfate extended-release (ER) tablets 30mg and 60mg

Lot Number

Morphine sulfate ER tablets 30mg: 179642

Morphine sulfate ER tablets 60mg: 179643

Expiration Date

Morphine sulfate ER tablets 30mg: 11/30/2023

Morphine sulfate ER tablets 60mg: 8/31/2023

Company:

Bryant Ranch Prepack Inc.

QUESTIONS

Call Bryant Ranch Prepack at 877.885.0882 Monday – Friday from 7:30 a.m. to 5:00 p.m. PDT.

Email Bryant Ranch Prepack at: cs@brppharma.com

Morphine Sulfate ER Tablets

It is for this reason that we are notifying you that on 06/29/2022 the US Food and Drug Administration published a drug recall for the following product(s): Morphine sulfate extended-release tablets 30mg and 60mg.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Bryant Ranch Prepack Inc. is voluntarily recalling one lot of morphine sulfate 30mg ER tablets (comprised of 10 bottles), and one lot of morphine sulfate 60mg ER tablets (comprised of 10 bottles) to the consumer level.

The products have been found to have incorrect labeling where bottles labeled as morphine sulfate 60mg ER tablets contain morphine sulfate 30mg ER tablets and bottles labeled as morphine sulfate 30mg ER tablets may contain morphine sulfate 60mg ER tablets.

For patients that have been prescribed the 30mg dose who receive the 60mg dose, it could put them at a higher risk for an overdose and death. Patients prescribed the 60mg dose who receive the 30mg 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, and retailers that have these products which are being recalled should stop using and contact Bryant Ranch Prepack Inc.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2022-038 June 2022

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urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2022). Bryant Ranch Prepack Inc. Issues Voluntary Nationwide Recall of Morphine Sulfate 30mg Extended-Release and Morphine Sulfate 60mg Extended-Release Due to Label-Mix Up. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bryant-ranch-prepack-inc-issues-voluntary-nationwide-recall-morphine-sulfate-30-mg-extended-release
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda