COMMUNICATION

2021-049

OCTOBER 2021

URGENT PLEASE REVIEW PharmPix Clinical Department

U.S. Food & Drug Administration Publication Date:

D

May

Cause

10/19/2021

Drug Information:

National Drug Code 7133-5179-52, 7133-5179-54, 7133-5179-57

Product Description Methocarbamol 500mg tablet

Lot Number 163935

Expiration Date

October 2022

Company:

Bryant Ranch Prepack

QUESTIONS

Call Bryant Ranch Prepack at 877-885-0882

Monday – Friday from 7:00 a.m. to 6:00pm PST.

Email: compliance@brppharma.com



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.

Methocarbamol

It is for this reason that we are notifying you that, on 10/19/2021, the US Food and Drug Administration published a drug recall for the following product(s): Methocarbamol 500mg tablets.

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 is voluntarily recalling 1 lot of methocarbamol 500mg tablets to the consumer level. The bottles labeled as methocarbamol 500mg tablets have been found to contain methocarbamol 750mg tablets.

If a patient takes a 750mg tablet of methocarbamol instead of the prescribed 500mg tablets, it potentially could result in excessive central nervous system depression which may result in nausea, sedation, fainting, falls, seizure, coma, and death. Bryant Ranch Park has not received any reports of adverse events related to this recall.

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



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-2021-049 October 2021





REFERENCES:

1. U.S. Food and Drug Administration. (2021). Bryant Ranch Prepack Issues Voluntary Nationwide Recall of Methocarbamol 500mg Bottles Due to Mislabeling With the Incorrect Strength.

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bryant-ranch-prepack-issues-voluntary-nationwide-recall-methocarbamol-500mg-bottles-due-mislabeling 2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. <u>https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda</u>

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