March 11, 2021 COM-2021-014

RECALL NOTIFICATION

FDA PUBLICATION DATE: March 9, 2021

DRUG NAME: Spironolactone 25MG and 50MG tablets

COMPANY: Bryant Ranch Prepack – BRP Pharmaceuticals

REASON: Incorrect strength displayed on the label

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on January 9, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary recall for four lots of Spironolactone 25mg and 50mg tablets manufactured by BRP Pharmaceuticals.

Affected product:

NDC	Product description	Lot #	Expiration Date
63629106401	**Spironolactone 25 mg Tablets**	148969	7/31/2022
63629106402		148791	
63629106403		148991	
63629106701	**Spironolactone 50 mg Tablets**	148992	5/31/2022

The voluntary recall is due to drug strength mislabeling. The spironolactone 25mg bottles may contain spironolactone 50mg tablets and vice versa.

Pharmacy required actions(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returning 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 for guidance or a replacement prescription.

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- Advise patients to contact their healthcare provider if they have experienced any problems related to using this drug product.

Contact information: For further details, contact Bryant Ranch Prepack at 877-885-0882 Monday to Friday 6:30 am to 6:00 pm PST.

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program in any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download the 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:

- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bryant-ranch-prepack-issues-voluntary-nationwide-recall-spironolactone-25-mg-and-50-mg-tablets-due

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2021). Bryant Ranch Prepack Issues Voluntary Nationwide Recall of Spironolactone 25 mg and 50 mg Tablets Due to Mislabeling with the Incorrect Strength (Revision to Press Release with Same Title Dated 3/9/2021. Revision Includes Number of Bottles Impacted by Recall). Retrieved January 10 2021, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bryant-ranch-prepack-issues-voluntary-nationwide-recall-spironolactone-25-mg-and-50-mg-tablets-due

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