Bryant Ranch Prepack Issues Voluntary Nationwide Recall of Spironolactone 25 mg and 50 mg Tablets Due to Mislabeling with the Incorrect Strength

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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 spironolactone tablets.

About this recall:
Bryant Ranch Prepack is voluntarily recalling in total 47 bottles of spironolactone tablets (4 different lots) to the consumer level. The products have been found to be mislabeled, displaying the incorrect strength. Prepackaged bottles labeled spironolactone 50 mg may contain spironolactone 25 mg tablets and prepackaged bottles of spironolactone 25 mg may contain spironolactone 50 mg tablets.

What this means to you:
A patient who takes spironolactone 25 mg instead of the prescribed spironolactone 50 mg may have an increase in blood pressure or increase in swelling due to excess fluid (edema). It is possible that patients could have a decrease in potassium, if taking half of the expected dose, which could lead to low potassium levels or hypokalemia, a condition associated with heart rhythm disorders. Additionally, patients who take spironolactone 50 mg instead of the prescribed spironolactone 25 mg could have an increase in potassium, which could be life-threatening. Patients with decreased kidney function or those taking certain other medications (for example: RAAS inhibitors, such as lisinopril, captopril, and others) would be at increased risk.

Consumers with questions regarding this recall can contact Bryant Ranch Prepack at 877-885-0882 Monday through Friday 6:30 am to 6 pm PST. 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: 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.

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-issues-voluntary-nationwide-recall-spironolactone-25-mg-and-50-mg-tablets-due

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 select prompt #2.