COMPANY ANNOUNCEMENT

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



## Summary

**Company Announcement Date:**

March 09, 2021

**FDA Publish Date:**

March 09, 2021

**Product Type:**

Drugs

**Reason for Announcement:**

Incorrect strength displayed on the label

**Company Name:**

Bryant Ranch Prepack

**Brand Name:**

BRP Pharmaceuticals

**Product Description:**

Spironolactone TB 25MG and 50MG

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## Company Announcement

Bryant Ranch Prepack is voluntarily recalling 4 lots of Spironolactone tablets 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.

A patient who consumes spironolactone 25 mg instead of the prescribed spironolactone 50 mg may experience an elevation in blood pressure or increased swelling caused by excess fluid (edema) if taking the product chronically. It is possible that patients could experience a decrease in potassium if taking half of the expected dose which could lead to Hypokalemia, a condition associated with cardiac arrhythmias. Furthermore, patients who consume spironolactone 50 mg instead of the prescribed spironolactone 25 mg could experience an increase in potassium which could be life-threatening. Patients with renal insufficiency or those taking concomitant renin-angiotensin-aldosterone system (RAAS) inhibitors would be at increased risk. As of 3/9/2021 Bryant Ranch Prepack has not received any reports of adverse events related to this recall.

Spironolactone is indicated as a diuretic in the treatment of high blood pressure, heart failure, hypokalemia, and edema and is repackaged in 30, 60 and 90-count bottles.

Lots included in recall:

| Product Description | NDC | Lot # (Expiration Date) |
|---|---|---|
| Spironolactone 25 mg Tablets | 63629106401 | 148969 (7/31/2022) |
| | 63629106402 | 148791 (7/31/2022) |
| | 63629106403 | 148991 (7/31/2022) |
| Spironolactone 50 mg Tablets | 63629106701 | 148992 (5/31/2022) |

The product can be identified by the following details on the label: Medication name as listed above with strength in a bold black box and a red and blue “BRP Pharmaceuticals” logo. Photos of the labels are provided in the photo section below.

Bryant Ranch Prepack is notifying its distributors and customers by mail and is arranging for return of all recalled products. Distributors that have existing inventory of any of the lots listed in this recalled should contact Bryant Ranch Prepack immediately.

Consumers with questions regarding this recall can contact Bryant Ranch Prepack at 877-885-0882 Mon.-Fri. 6:30am-6pm 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)

- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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 U.S. Food and Drug Administration.

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## Company Contact Information

**Consumers:**

Bryant Ranch Prepack

877-885-0882

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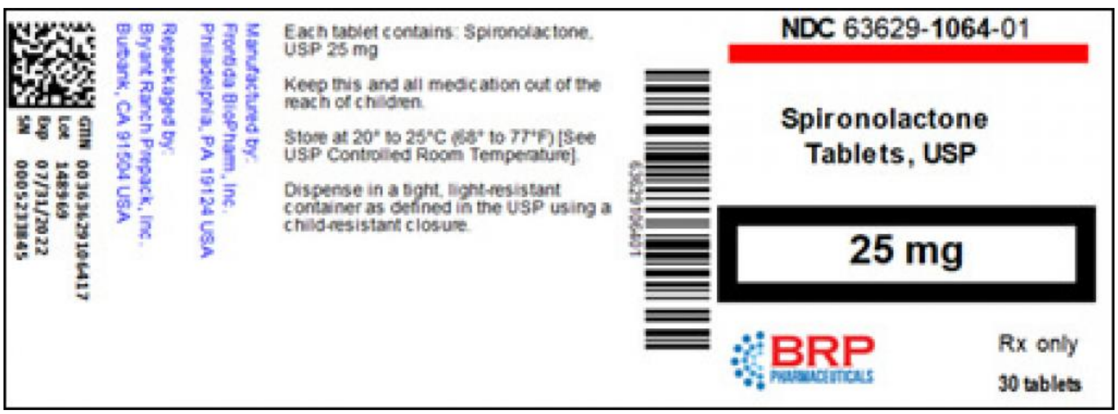
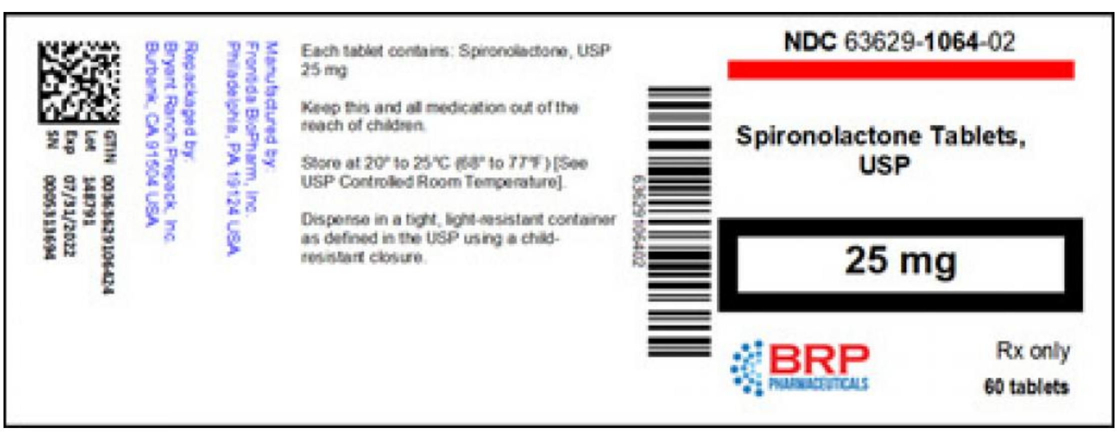
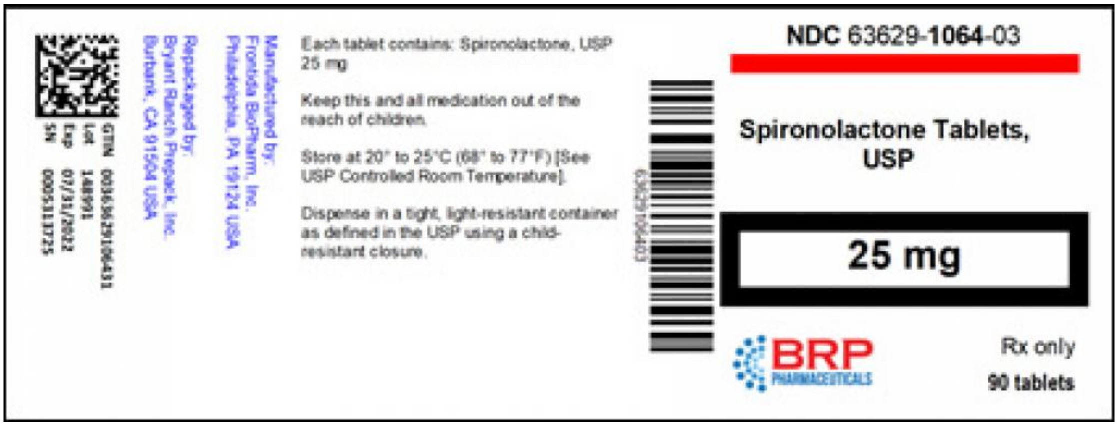
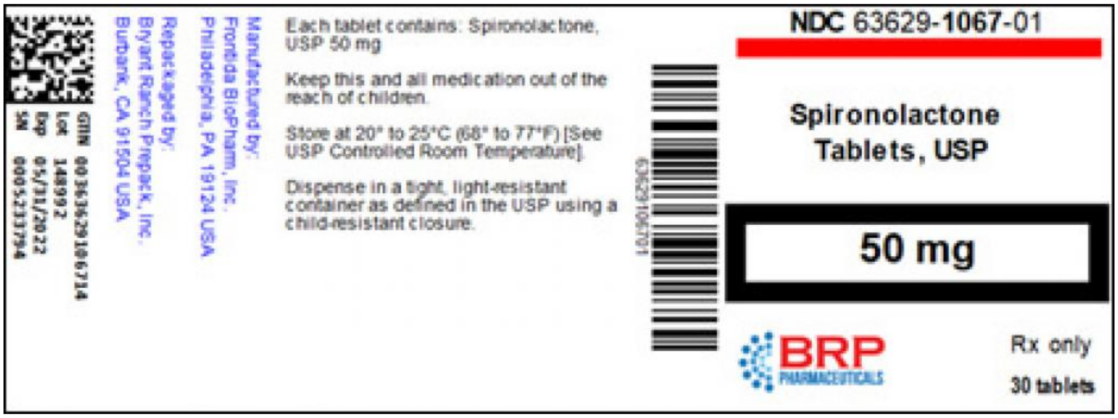
## Product Photos






More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)