

STASON PHARMACEUTICALS, INC.

Stason Pharma
Irvine, CA
Facility

11 Morgan, Irvine, California 92618 Telephone (949) 380-4327 Fax (949) 380-4345

URGENT: Stason Pharmaceuticals, Inc. Mercaptopurine Tablets, USP 50 mg RECALL

February 9, 2024

Michelle Cohen
Independent Pharmacy Distributor
1107 W. Market Center Drive
High Point, NC 27260

Dear Michelle:

This is to inform you of a product recall involving:

Mercaptopurine Tablets, USP 50 mg in the following Lots:

22K012, Expiration 04/2024 (25 tablets/bottle)
22K013A, Expiration 04/2024 (25 tablets/bottle)
22K013B, Expiration 04/2024 (250 tablets/bottle)
23A001, Expiration 07/2024 (25 tablets/bottle)
23A002A, Expiration 07/2024 (25 tablets/bottle)
23A002B, Expiration 07/2024 (250 tablets/bottle)
23D006, Expiration 10/2024 (25 tablets/bottle)
23D007A, Expiration 10/2024 (25 tablets/bottle)
23D007B, Expiration 10/2024 (250 tablets/bottle)
23D007C, Expiration 10/2024 (25 tablets/bottle)

Please see the enclosed product label for ease in identifying the product.

This recall has been initiated due to an ***Out of Specification test result for Dissolution.***

An Initial Field Alert Report was submitted on December 21, 2023 by Stason Pharmaceuticals, Inc. (NDA Holder and manufacturer), for an Out of Specification result for Dissolution test observed during stability analysis in one batch. A Follow-up Field Alert Report has been submitted on January 31, 2024 to report additional lots identified within the same scope.

The product in the lots mentioned above started shipping on November 17, 2022. We had supplied the above-mentioned product to you on between November 17, 2022 – September 27, 2023.

You are hereby advised to return all remaining stocks available with you to our third-party logistics warehouse care of DCS, Direct Customer Solutions, 4277 Highway 412 S, Bells, TN 38006-3901.

Shipping arrangements and refunds will be made for all products recalled.

Please do not distribute or sell the product.

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No adverse events have been reported for Mercaptopurine Tablets regarding lack of effect or otherwise related issues since the affected lots have been manufactured and distributed.

Risk of Consuming Recalled Product: Tablets from the lots subject to recall are dissolving slower than the FDA imposed dissolution specification, which is tighter than USP. Consumption of this product may have delayed effect.

Manufacturing and distribution of the product for both 25ct/bottle and 250ct/bottle, has ceased. Stason Pharmaceuticals, Inc., has informed the FDA field office that it has ceased manufacturing of the drug product **Mercaptopurine Tablets, USP 50 mg** and that it intends to withdraw all unexpired lots of the product in the market from distribution.

Please immediately examine your inventory and quarantine the product subject to recall.

This recall should be carried out to the wholesale level and your assistance is greatly appreciated.

Please complete and return the enclosed **Return Response Form** as soon as possible to sandy@quinnrx.com.

If you have any questions, please call Candy Caine at 561-609-3240 x 246, M – F @ 9:00 am – 4:00 PM EST, who will coordinate with a Stason Pharmaceuticals, Inc. representative.

This recall is being made with the knowledge of the Food and Drug Administration.

Thank you,



CEO
Stason Pharmaceuticals, Inc.
949-380-4327

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Copy of Labels

- Mercaptopurine Tablets, USP 50 mg, 25 ct. bottle

NDC 69076-913-02

Mercaptopurine Tablets, USP

50 mg

Each tablet contains 50 mg mercaptopurine.
Cytotoxic Agent
Carefully read warning and accompanying package insert for dosage information.



Rx only
25 Tablets

WARNING: This drug is only to be taken under close medical supervision. Do not take in larger doses or more frequently or for a longer time than specifically directed by the physician. Periodic blood counts are necessary to determine proper dose and to avoid ill effects. Store at 20° to 25°C (68° to 77°F). See USP Controlled Room Temperature. Store in a dry place. Dispense in tight container as defined in the USP.

Manufactured for: Quinn Pharmaceuticals
Boca Raton, FL 954-755-0502
www.quinnrx.com
Made in U.S.A.

Rev. 02/21



N 3 69076 91302 8


- Mercaptopurine Tablets, USP 50 mg, 250 ct. bottle

NDC 69076-913-25

Mercaptopurine Tablets, USP

50 mg

Each tablet contains 50 mg mercaptopurine.
Cytotoxic Agent
Carefully read warning and accompanying package insert for dosage information.



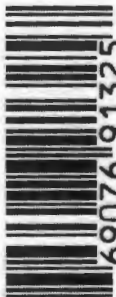
Rx only
250 Tablets

WARNING: This drug is only to be taken under close medical supervision. Do not take in larger doses or more frequently or for a longer time than specifically directed by the physician. Periodic blood counts are necessary to determine proper dose and to avoid ill effects.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Store in a dry place. Dispense in tight container as defined in the USP.

Manufactured for:
Quinn Pharmaceuticals
Boca Raton, FL
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Rev. 02/21



N 3 69076 91325 7