Alembic Issues Voluntary Nationwide Recall of Telmisartan Tablets, USP, 20 mg Due to Label Mix-Up

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Alembic is voluntarily recalling 1 lot of telmisartan tablets, USP, 20 mg, packaged in 30-count bottles (lot number 1905005661) to the consumer level. The product is being recalled due to a market complaint received which stated that 1 bottle labeled as 30-count telmisartan tablets, USP, *20 mg,* incorrectly contained 30 tablets of telmisartan tablets, USP, *40 mg*.

Risk Statement: Patients who receive a doubled dose of telmisartan for a prolonged period of time could experience low blood pressure, worsening of kidney function, or an elevation of potassium which can be life-threatening. To date, Alembic has not received any reports of adverse events related to this recall.

Telmisartan is used for the treatment of hypertension (to lower blood pressure) and is packaged in a bottle of 30 tablets with NDC 62332-087-30. The impacted lot of telmisartan tablets, USP, 20 mg is lot number 1905005661 with an expiration date of March 2022. The wrong product can be identified by checking the shape and embossing details on the tablets; telmisartan tablets, USP, 20 mg, bottles may incorrectly contain oval shaped, white to off-white tablets debossed with L203 on one side instead of correct product (round shaped, white to off-white tablets debossed with L 202 on one side). Telmisartan tablets, USP, 20 mg, lot number 1905005661 was distributed nationwide in the United States (US) to wholesalers, retailers, and pharmacies.

Alembic is notifying its distributors and retailers through letter and is arranging for return of the recalled lot. The FDA instructs consumers that may have telmisartan tablets, USP, 20 mg, that are being recalled *not* to discontinue use until speaking with their pharmacist or healthcare professional (HCP) about a replacement, before returning to the place of purchase. Consumers with questions regarding this recall can contact Alembic by phone at 1-908-552-5839 (9 am to 5 pm, EDT, Monday through Friday) or by email at david.cobb@alembicusa.com. Consumers should contact their physician or HCP 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.

This recall is being conducted with the knowledge of the US Food and Drug Administration (FDA).

Link to FDA recall notification: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alembic-pharmaceuticals-limited-issues-voluntary-nationwide-recall-telmisartan-tablets-usp-20-mg-due

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Company Contact Information

Consumers:

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Product Photos

Click here for product photos.