COMPANY ANNOUNCEMENT

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

Summary

Company Announcement Date:

March 24, 2021

FDA Publish Date:

March 24, 2021

Product Type:

Drugs

Reason for Announcement:

Incorrect Product Strength on Label

Company Name:

Alembic Pharmaceuticals, Inc.

Brand Name:

Alembic

Product Description:

Telmisartan Tablets, USP, 20 mg

Company Announcement

Bridgewater, NJ, Alembic Pharmaceuticals, Inc is voluntarily recalling one lot of Telmisartan Tablets, USP, 20 mg, packaged in 30-count bottles, Lot No. 1905005661 to the consumer level. The product is being recalled due to a market complaint received which stated that one bottle labelled as 30-count Telmisartan Tablets, USP, 20 mg incorrectly contained 30 tablets of Telmisartan Tablets, USP, 40mg.

Risk Statement: Patients who could be on 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 Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

The product is used for the treatment of hypertension i.e. to lower blood pressure and is packaged in a bottle of 30 tablets having NDC Number 62332-087-30. The affected lot of Telmisartan Tablets, USP, 20 mg is the lot number 1905005661 and the lot expires in March 2022. The wrong product can be identified by checking the shape and embossing details on the tablets i.e. 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 i.e. round shaped White to off-white tablets debossed with L 202 on one side. Telmisartan Tablets, USP, 20mg, Lot No. 1905005661 was distributed Nationwide in the USA to wholesalers, retailers, and pharmacies.

Alembic Pharmaceuticals Limited is notifying its distributors and retailers through letter and is arranging for return of the recalled lot. Consumers that may have Telmisartan Tablets, USP, 20 mg which is being recalled should not discontinue use until speaking with their pharmacist or healthcare professional for a replacement before returning to place of purchase.

Consumers with questions regarding this recall can contact Alembic Pharmaceuticals Inc by phone at +1 908-552-5839 (9:00 am – 5:00 pm, EDT, Monday through Friday) or email address david.cobb@alembicusa.com (mailto:david.cobb@alembicusa.com). 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.

Company Contact Information

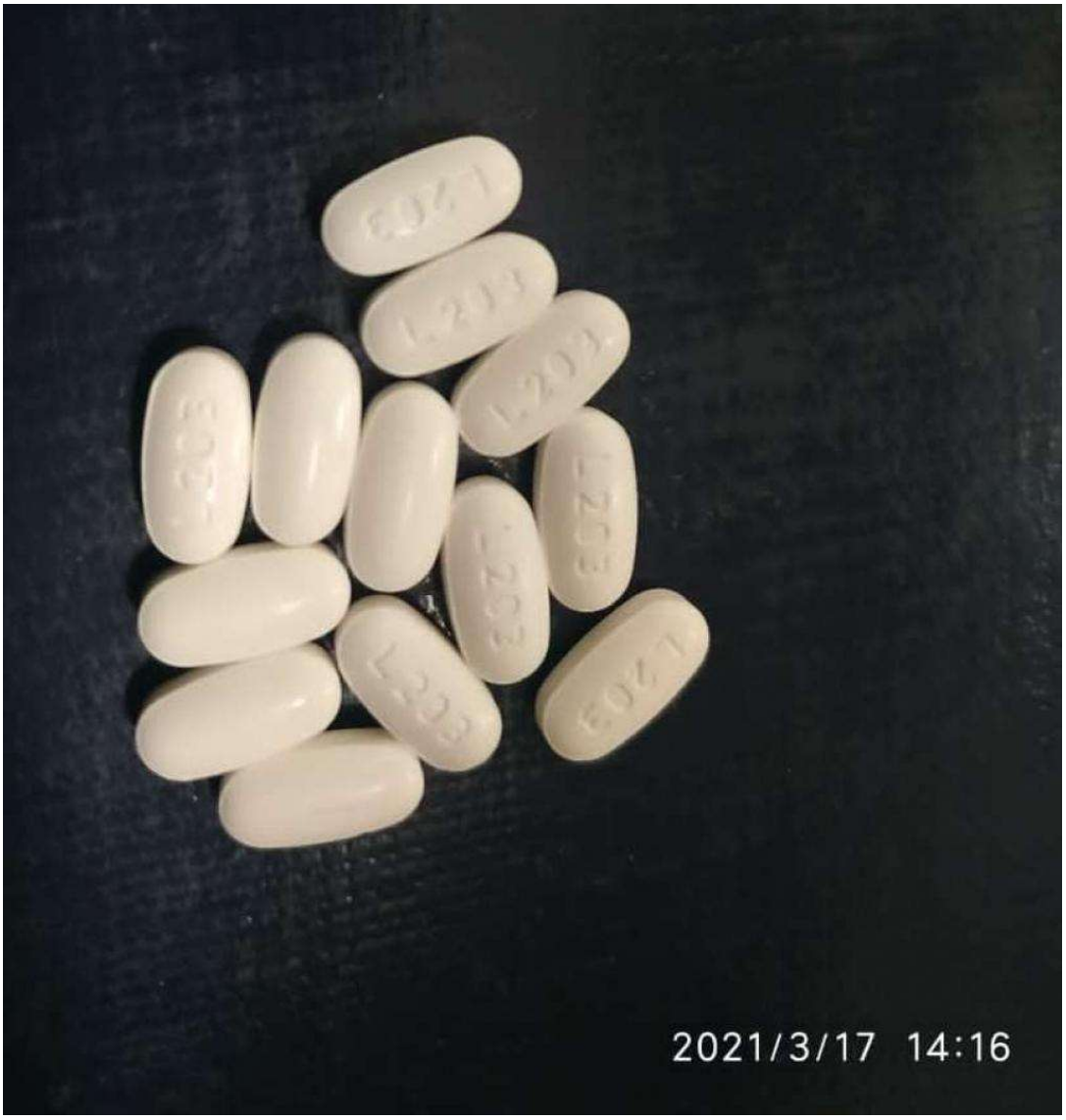
Consumers:

Alembic Pharmaceuticals, Inc.

+1-908-552-5839

david.cobb@alembicusa.com (mailto:david.cobb@alembicusa.com)

Product Photos



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