March 25, 2021

COM-2021-016

RECALL NOTIFICATION

FDA PUBLICATION DATE:

March 24, 2021

DRUG NAME: Telmisartan tablets, USP 20mg

COMPANY: Alembic Pharmaceuticals

REASON: Incorrect Product Strength on Label

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on March 24, 2021, the US Food and Drug Administration (FDA) published a voluntary drug recall for one lot of the following product: Telmisartan Tablets, USP 20 mg, manufactured by Alembic Pharmaceuticals, Inc.

Affected product:

NDC	Product description	Lot #	Expiration Date
62332-0087-30	Telmisartan Tablets, USP 20 mg (generic equivalent to Micardis tablets)	1905005661	03/2022

The voluntary recall is due to a market complaint received which stated that one bottle labeled as 30-count Telmisartan Tablets, USP, 20 mg incorrectly contained 30 tablets of Telmisartan Tablets, USP, 40mg. Telmisartan is used for the treatment of hypertension. Patients who could be on a doubled dose of telmisartan for a prolonged period could experience low blood pressure, worsening of kidney function, or an elevation of potassium which can be life-threatening. Patients should not discontinue use until speaking with their pharmacist or healthcare professional for a replacement before returning to the place of purchase.

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Pharmacy required action(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- Advise patients to contact their physician if they have experienced any problems related to taking or using this product.

Contact information: For further details, contact Alembic Pharmaceuticals, Inc. at phone number 908-552-5839 or email david.cobb@alembicusa.com.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2021). Alembic Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Telmisartan Tablets, USP, 20 mg Due to Label Mix-Up. Retrieved March 25, 2021 from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alembic-pharmaceuticals-limited-issues-voluntary-nationwide-recall-telmisartan-tablets-usp-20-mg-due