Torrent Pharmaceuticals Limited's Nationwide Recall of Valsartan/Amlodipine/HTCZ, Valsartan/Amlodipine, and Valsartan Tablets

On August 17, 2018, the FDA advised healthcare professionals of a nationwide recall of all lots of Torrent Pharmaceuticals Limited manufactured valsartan/amlodipine/HCTZ, valsartan/amlodipine, and valsartan tablets. Zhejiang Huahai Pharmaceuticals detected trace amounts of an unexpected impurity found in an active ingredient in one of their manufactured drugs. The impurity detected was N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in many products. Due to the impurity found, Torrent Pharmaceuticals Limited voluntarily recalled all lots of their manufactured valsartan-containing products. Torrent joins other manufacturers, such as Major Pharmaceuticals, Solo Healthcare, and Teva Pharmaceuticals who have already recalled their valsartan products[1].

NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. NDMA contamination may be found in air, soil and water. Exposure to high levels of NDMA can cause liver damage in humans. Potential symptoms of NDMA overexposure in humans include headache, fever, nausea, jaundice, vomiting, abdominal cramps, dizziness, enlarged liver, and reduced function of liver, kidneys, and lungs. Studies completed in rodents have shown that exposure to NDMA in various routes caused liver, respiratory tract, kidney and blood vessel tumor formation. These studies led organizations such as the Department of Health and Human Services (DHHS), Environmental Protection Agency (EPA), and International Agency for Research on Cancer (IARC) to reasonably classify NDMA as a probable human carcinogen[2].

The FDA recall recommends that patients on valsartan continue taking their prescribed medication, as the risk of harm may be higher if the treatment is stopped immediately without any alternative treatment[1]. Patients are advised to speak to a pharmacist or physician who can counsel them on alternative therapies.

References:

1. Recalls, Market Withdrawals, & Safety Alerts. UPDATED: Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Valsartan/Amlodipine/HCTZ, Valsartan/Amlodipine and Valsartan Tablets. U.S. Food and Drug Administration. 2018. Available at: https://www.fda.gov/Safety/Recalls/ucm617821.htm
2. N-Nitroso-dimethylamine (NDMA). Technical Fact Sheet. United States Environmental Protection Agency. 2014. Available at: https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf

Casey Bardsley, PharmD Candidate