Marksans Pharma – Recall metformin extended-release (ER)

- On October 5, 2020, Marksans announced a voluntary, consumer-level recall of an additional 76 lots of metformin extended release tablets due to the level of N-Nitrosodimethylamine (NDMA), which has been found to be above the allowable Acceptable Daily Intake (ADI) limit established by the FDA.
    - This is an expansion to the recall that was announced in June 2020.
    - Marksans performed NDMA testing of unexpired identified marketed lots and observed that NDMA content in some lots exceeded the acceptable ADI, thus additional lots are being recalled.
    - See Marksans announcement for a complete list of the recalled lots.
- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
- Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.
- Patients taking metformin ER are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment.
- According to the FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals. See here for more information about metformin products and NDMA contamination.
- Patients who have the recalled metformin ER should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled metformin ER.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact Time-Cap Labs (appointed company for Marksans) by phone at **1-631-753-9090 ext. 160** or by email at **imcgregor@timecaplabs.com** for further information regarding this recall.