

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Rising Pharma Holdings, Inc is initiating a recall to the Retail level for Temozolomide Capsules, USP 5 mg, batch # 1TM0524003A.

This recall is being initiated based on an out-of-specification result observed during 9th-month long term stability testing (25°C/60% RH) for organic impurities by HPLC. The result for "any unspecified degradation product" was found at 0.20%, exceeding the specification limit of NMT 0.10%.

Based on a detailed investigation, the root cause was identified as improper induction sealing leading to moisture ingress and subsequent out of specification results in a small number of containers. However, as a precautionary measure, a voluntary recall of entire batch is being initiated.

Rising also conducted a comprehensive health hazard assessment, which determined that the overall patient's health risk is low. Given the limited scope of affected units (<2%), the controlled oncology treatment setting, and active patient monitoring, no additional health risk is expected to meaningfully affect patient outcomes.

This product was shipped between the dates of 11/2024 – 05/2025.

PRODUCT: Temozolomide Capsules USP 5 mg

NDC NUMBER: 16571-816-51

BATCH NUMBER: 1TM0524003A

EXPIRATION DATE: 09/2026

DISTRIBUTION DATES: 11/2024 – 05/2025