

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.

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a recall of 2 lots of Clobetasol Propionate Cream USP 0.05% (60 g pack size) to the retail level.

These drug product lots are being recalled due to out-of-specification (OOS) results observed for the Uniformity in Containers test during long-term stability studies. The OOS results were associated with the absolute difference between assay values obtained from individual containers; however, the individual assay results remained within the approved specification limits. All other quality attributes tested during stability studies were found to be within established acceptance criteria.

Clobetasol Propionate Cream USP, 0.05% is a topical dosage form, thus the actual dose delivered to a patient depends on several factors, including the amount of product applied, the size and location of the treatment area, the frequency and duration of application, and individual patient use patterns. Therefore, the precise clinical impact of the observed variability cannot be accurately predicted; however, the review of Lupin's Safety Database did not identify any safety concerns or potential adverse events that could be attributed to the issue under discussion.

The product can be described as a white to off white homogenous cream without any phase separation; free from foreign particles and lumps, packed in sealed orifice. Aluminum collapsible tube with inner lacquer, crimp sealant and reverse FEZ cap.

PRODUCT: Clobetasol Propionate Cream USP 0.05%, 60g tube

NDC NUMBER: 68180-956-04

LOT NUMBER	EXPIRATION DATE
KB00427	04/2028
KA00308	10/2026