

*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.*

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a nationwide recall of the above one (1) lot of Testosterone Gel 1%, 2.5 grams, CIII, for topical use, to the RETAIL LEVEL. The product in this recall is distributed under the Actavis Pharma Inc. label. The reason for the recall is that a defect in the side-seal was discovered in packets of Testosterone Gel 1% from lot # 100068692, making it possible for the gel product to leak from the packets. The primary health concern associated with this defect is a potential reduction in treatment efficacy due to underdosing of testosterone. This may lead to insufficient control of testosterone deficiency disorders, resulting in inadequate management of the underlying condition (deficiency or absence of endogenous testosterone). Teva's health hazard assessment concluded that exposure to the product of concern could lead to mild adverse events, and the likelihood of harm occurrence is possible. Consequently, the overall risk of harm in the patient population is considered to be low.

This recall is being made with the knowledge of the Food and Drug Administration.

PRODUCT: Testosterone Gel 1%, 2.5 grams, CIII, for topical use

NDC NUMBER: Carton NDC: 0591-3216-30    Packet NDC: 0591-3216-17

LOT NUMBER: 100068692

EXPIRATION DATE: 04/2027