<<Date>>

<<First Name>> <<Last Name>>
<< Address line 1>>
<< Address line 2>>
<<City>> <<ST>> << Zip Code>>

RECALL NOTICE

Dear <<First Name>> <<Last Name>>,

Our records indicate that you may have recently received a prescription for Testosterone Gel 1% 25 mg/2.5 g per unit dose distributed by Actavis Pharma, Inc. from your retail pharmacy. We are writing to inform you of a limited recall that has been issued for one lot of this product.

On July 25, 2022, the United States Food and Drug Administration (FDA) published its classification of the recall of one lot of Testosterone Gel 1% manufactured by Actavis Pharma, Inc., as a Class II recall. According to the manufacturer, this recall was initiated because an out of specification assay result was obtained during stability testing. Specifically, according to the recalling firm, Teva Pharmaceuticals USA, Inc., the product may have slightly higher concentrations of testosterone, and the main safety concern that may arise from a slightly higher assay limit for testosterone is a higher risk of experiencing adverse events associated with testosterone replacement therapy. Teva's health hazard assessment concluded that use of product of concern might lead to moderate adverse events. Common adverse events associated with testosterone replacement therapy include application site reactions (e.g. skin irritation), acne, lab tests changes (e.g., elevated hemoglobin or hematocrit, elevated triglycerides, hyperlipidemia, etc.), and elevated prostate specific antigen (PSA). Patients with benign prostatic hyperplasia (BPH) treated with androgens are at increased risk for worsening signs and symptoms of BPH. **Teva issued this recall on June 29, 2022 to wholesalers and pharmacies only and is not requiring any action on the part of consumers in this recall.**

Product: Testosterone Gel 1% 25 mg/2.5 g per unit dose
NDC: 00591-3216-17 (single packet), 00591-3216-30 (30 count)
Lot Number/Expiration Date: 1403180 exp. 10/2022

Please contact your prescriber with any questions or concerns about this recall or your use of the product.

For more information, please call Teva Pharmaceuticals USA, Inc. toll-free at 1-888-838-2872. You may also call the U.S. Food and Drug Administration toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit www.fda.gov.

- This material is available in other languages. Please call our member services department at the toll-free number listed on your benefit ID card. TTY users should call 1-800-863-5488.

- Esta información está disponible en otros idiomas. Por favor llame a nuestro departamento de servicios al cliente al número gratuito que aparece en su tarjeta de identificación. Los usuarios de equipo teleescritor (TTY) deben llamar al 1-800-863-5488.

Sincerely,

CVS Caremark®