

Taro Issues Voluntary Nationwide Recall of Clobetasol Propionate Ointment USP, 0.05%, 60 g Tubes, Lot AC13786 Due to Microbial Contamination

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Taro Pharmaceuticals is voluntarily recalling one (1) lot of Clobetasol Propionate Ointment USP, 0.05% packaged in 60 g tubes to the consumer level. This recall ONLY applies to tubes labeled with “Lot AC13786” and “Exp Dec 2022”. No other lots of this product are impacted. This lot is being recalled due to the presence of *Ralstonia pickettii* bacteria (*R. pickettii*), which was discovered by the manufacturer through routine testing.

R. pickettii is present in the environment (soil, water) and for healthy individuals with intact skin, is unlikely to cause any localized or systemic infections. However, for individuals who are immunocompromised or whose skin is not intact (sunburn, psoriasis, abrasions), there is a reasonable possibility that systemic infections may occur if the product is contaminated with *R. pickettii*. This is due to the presence of the corticosteroid component which enhances absorption of the ointment. If this bacterium is circulating in the human blood stream it can cause life-threatening, invasive infections such as sepsis, pneumonia, meningitis, inflammation of the bone or bone marrow, and infection in the joint fluid and joint tissues. To date, Taro has not received any adverse event reports related to this lot.

The lot being recalled is listed in the table:

Lot #	Amount	Expiration Date
AC13786	96 units	December 2022

Clobetasol Propionate Ointment USP, 0.05% is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses and is packaged in 60 g aluminum tubes with polypropylene puncture-tip caps. Each 60 g tube is labeled to indicate the name of the product, Clobetasol Propionate Ointment USP, 0.05% and the NDC # 51672-1259-03 (image of container label is linked on the following page). The lot number and expiration date are displayed on the bottom of each tube and the end flap of the product carton.

Ninety-six (96) units of lot AC13786 were distributed to two wholesale distributors in the United States (US) market between November 16 and December 6, 2021. These two wholesale distributors may have further distributed this lot to their retail customers for prescription dispensing to patients who were prescribed Clobetasol Propionate Ointment USP, 0.05%, 60 g.

Taro has notified the affected distributors by phone, e-mail, and letters via US Mail and is arranging for return of any containers of Clobetasol Propionate Ointment USP, 0.05%, 60 g, Lot AC13786 (expiration date of December 2022). Retail customers that have any quantities of Lot AC13786 which is being recalled, should stop distribution and return any unsold units to their wholesaler.

Consumers with questions regarding this recall can contact Taro by calling 1-866-923-4914 or by e-mail at TaroPVUS@taro.com, Monday through Friday between 7 am and 7 pm, US Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Company Contact Information

Consumers:

Taro Pharmaceuticals U.S.A., Medical Information

1-866-923-4914

TaroPVUS@taro.com

Product Photos

Click [here](#) for product photos.