

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

Date: 12/30/2021

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Taro Pharmaceuticals has posted a lot recall of Clobetasol Propionate Ointment 0.05%, 60 g tubes.

About this recall:

Taro is voluntarily recalling one (1) lot of Clobetasol Propionate Ointment USP, 0.05% packaged in 60 gram tubes, to the consumer level. The product is being recalled due to microbial contamination. **This recall only applies to tubes labeled with “Lot AC13786” and “Exp Dec 2022.”**

What this means to you:

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 natural 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), the potential exists that systemic infections may occur if the product is contaminated with *R. pickettii*. This is due to the presence of the steroid component which increases absorption of the ointment. If this bacterium circulates 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 product is used for the relief of inflammation and itching of the skin that is responsive to steroids. **It is packaged in 60 gram aluminum tubes labeled with the name of the product, Clobetasol Propionate Ointment USP, 0.05% and the NDC # 51672-1259-03** (image of container label hyperlinked 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.

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

For more information regarding this FDA Recall Notification, please refer to the FDA website:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall-clobetasol-propionate-ointment-usp-005>

FDA contact information for reporting adverse events/quality complaints can be reached online at <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home> or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.