

Clobetasol Propionate Ointment 0.05%

Hawthorne, NY, December 27, 2021 – Taro Pharmaceuticals U.S.A., Inc. (“Taro” or the “Company”) 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. Lot AC13786 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 (i.e. sunburn, psoriasis, abrasions), there is a reasonable possibility that systemic infections may occur if the product is contaminated with *R. pickettii* 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 one (1) lot being recalled is as follows:

Lot #	Amount	Expiration Date
AC13786	96 units	December 2022

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 7:00 am and 7:00 pm, U.S. 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.