COMMUNICATION

2022-002

05 JANUARY 2022

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

12/30/2021

Drug Information:

National Drug Code

51675-1259-03

Product Description

Clobetasol propionate ointment USP 0.05%

Lot Number

AC13786

Expiration Date

December 2022

Company:

Taro Pharmaceuticals U.S.A., Inc.

QUESTIONS

Call Taro Pharmaceuticals at 1-866-923-4914 Monday – Friday from 7:00 a.m. to 7:00 p.m. CST.

Email: TaroPVUS@taro.com

Clobetasol Propionate Ointment

It is for this reason that we are notifying you that on 12/30/2021 the US Food and Drug Administration published a drug recall for the following product: Clobetasol propionate ointment USP, 0.05%.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Taro Pharmaceuticals U.S.A., Inc. is voluntarily recalling one lot of clobetasol propionate ointment USP, 0.05% packaged in 60 g tubes, to the consumer level.

Lot AC13786 has been 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 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, 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 blood stream it can cause life-threatening, invasive infections such 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. Ninety-six units of lot AC13786 were distributed to two wholesale distributors in the U.S. 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%.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2022-002, January 2022

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Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2021). Taro Pharmaceuticals U.S.A. Issues Voluntary Nationwide Recall of Clobetasol Propionate Ointment USP, 0.05%, 60 g Tubes, Lot AC13786 Due to Microbial Contamination. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall-clobetasol-propionate-ointment-usp-005
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda