



Urgent Recall Notification
Please Read Immediately

August 30, 2022

Dear Valued Customer;

On August 17th, Padagis US LLC initiated a wholesale level recall of one batch of **Triamcinolone Acetonide Cream USP, 0.1% 80 g** in the marketplace.

This recall has been extended to the pharmacy level. Customers that may have further distributed this product are requested to contact their customers and notify them immediately of this product recall.

Batch 2CT0486 is being recalled due to a trend of product complaints reporting the product to have a gritty texture. The texture change is caused by larger oil phase droplets inherent to the formulation. At this time, no serious adverse events have been reported or are known.

Please note, the referenced drug product batch is labeled with Perrigo trade dress.

This action is being taken with the knowledge of the FDA and is being issued to the pharmacy level. We are asking for returns of the affected batch from all warehouse and pharmacy locations. It is not necessary for pharmacy customers to notify patients who purchased this product.

We deeply regret any inconvenience and appreciate your assistance with this recall. Please refer to the Recall Notification Details document for aid in returning product. If we can provide any additional information or assistance, please contact Padagis Customer Service at 800-775-2054 or PadagisRxOrders@Padagis.com

Sincerely,

A handwritten signature in black ink, appearing to read "David Tyree".

David Tyree
Vice President, US Quality

Attachment: Recall Notification Details
Initial Response Form

Copy: Courtney Taylor, Recall Coordinator

Recall Notification Details
Triamcinolone Acetonide Cream USP, 0.1% 80 g
(Pharmacy Level)
August 2022

<p>Product</p>	<p>Product: Triamcinolone Acetonide Cream USP, 0.1% 80 g NDC: 45802-064-36 Strength: 0.1% Package Size: 80 grams Batch Numbers: 2CT0486 Exp: 02/29/2024 Manufactured By: Perrigo New York Please note the referenced drug product is labeled with Perrigo trade dress.</p> <p>Distribution Dates: 04/21/2022-06/23/2022</p>
<p>Reason</p>	<p>These batches are being recalled by Padagis due to a consumer complaint of gritty product texture.</p> <p>Health Hazard: Exposure to the affected product is not likely to cause any serious adverse health consequences from use.</p>
<p>Action</p>	<ol style="list-style-type: none"> 1. Stop dispensing and distributing and quarantine these batches 2. Forward this recall notification to any pharmacy locations that may have received the affected product. 3. Please carry out a physical count and record this data on the Initial response form and return as directed on the form. 4. Effectiveness Check: The FDA requires Padagis to verify notifications to determine the effectiveness of this recall. Padagis will begin making these effectiveness checks by phone within four weeks. 5. Return the recalled product within 60 days to: <p style="text-align: center;">Padagis Company Returns Attn: Triamcinolone Recall Padagis RA# 66000006 110 Hidden Lake Circle, Suite A Duncan, SC 29334</p> <p style="text-align: center;">For Call Tags please contact PadagisRxOrders@Padagis.com</p> <p style="text-align: center;">Please call 1-800-775-2054 with any questions</p>
<p>Credit</p>	<p>Credit will be issued for product returned under the correct RA # and matching the product's description above. Credit will only be issued for product from the affected batch returned within 60 days. Credit will be issued against a Padagis customer deduction.</p> <p>Credit may be denied if the RA# is not properly referenced at the time of the return or when the customer deduction is taken.</p>
<p>Other Information</p>	<p>This recall is only for the product and batch listed above. Notifications are being sent out to all the accounts that purchased this product from Padagis LLC.</p> <p>For medical questions contact Padagis Call Center at 1-866-634-9120 or Consumer.Support@Padagis.com</p> <p>We sincerely regret any inconvenience caused by this action and appreciate your immediate attention and cooperation.</p>

Triamcinolone Acetonide Cream USP, 0.1% 80 g
(Pharmacy Level)

PADAGIS COMPANY PRODUCT RECALL

Initial Response Form

Store Name:
Address:
City, State, Zip:
Phone:

Please return this form **within 3 days** by scanning the completed form and emailing to Recall@padagis.com. If you have any questions, please contact the Padagis Company Recall Coordinator at (763) 732-0533

1. Did you receive shipment of the product being recalled? (If no, please sign and return).	Yes	No
2. Do you currently have any of the recalled products remaining in inventory? Amount in inventory at this time _____	Yes	No
3. If the answer to question 2 is <u>Yes</u> , do you intend to return the product to the Padagis Company as requested?	Yes	No
4. If the answer to question 3 is <u>No</u> , please explain your intentions for the product.		
5. Have you received any reports of illness or injury related to this product that have not been previously reported? If yes, please call 1-866-634-9120 or Consumer.Support@Padagis.com to report these events.	Yes	No
6. For those customers that may have further shipped any of the recalled product, has notification about this recall has been forwarded?	Yes	No
Comments:		

Printed Name _____

Phone Number _____

Date _____