VIATRIS™

Urgent: Drug Recall
Proctofoam® HC
(hydrocortisone acetate 1% and pramoxine hydrochloride 1%)

Recall Initiated By: Mylan Specialty L.P. (a Viatris company)

Product Distributed By: Meda Pharmaceuticals Inc. (a Viatris company)

Product Manufacturer: Pharmasol Corporation, South Easton, MA

January 21, 2022

PRODUCT

NDC#	Name and Strength	Batch #	Size	Expires
0037-6822-10	Proctofoam® HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%)	32925	10 gram aerosol container	May 2023
0037-6822-10	Proctofoam® HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%)	33010	10 gram aerosol container	June 2023
0037-6822-10	Proctofoam® HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%)	33119	10 gram aerosol container	August 2023
0037-6822-10	Proctofoam® HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%)	33123	10 gram aerosol container	August 2023

REASON

Mylan Specialty L.P. (a Viatris company) is conducting a voluntary recall at the retail level of four batches of Proctofoam® HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%), distributed by Meda Pharmaceuticals Inc. (a Viatris company). The product is supplied in a 10 gram aerosol container with applicator. These four batches are being recalled, due to concerns expressed by FDA regarding good manufacturing deficiencies at Pharmasol, the manufacturer. These batches were distributed in the US between June 29, 2020 and June 23, 2021.

Proctofoam® HC is no longer manufactured by Pharmasol, and this recall is isolated to the batches indicated above.

Proctofoam® HC is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the anal region.

ACTION

Wholesaler:

1. Immediately examine your inventory, quarantine, and discontinue distribution of these batches.
2. In addition, if you have further distributed the product, please identify your retail level customers and provide a list of customers via Microsoft excel file to **Mylan5611@sedgwick.com** within 10 business days. Sedgwick will notify your retail level customers that received the affected batch.

Retailer: Immediately examine your inventory, quarantine and discontinue distribution of these batches.

Wholesaler and Retailer

1. Carry out a physical count and record this data on the Business Reply Card and Packing Slip which are included.
2. Mail the postage paid Business Reply Card to the address provided.

3. Return the recalled product with the Packing Slip using the prepaid UPS Return Service shipping labels to:
   Sedgwick
   Event # 5611
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

OTHER: This recall extends to the retail level.
Credit/check will be issued for return of recalled product only.
This recall is being conducted with the knowledge of the Food and Drug Administration.
For questions regarding the recall, please call Sedgwick at 1-800-386-4756.
Normal business hours are Monday through Friday 8AM to 5PM Eastern Standard Time.
Any other product returned that is not involved with this recall will be destroyed and credit will not be issued. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.