

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Proctofoam® HC

(hydrocortisone acetate 1% and pramoxine hydrochloride 1%)

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

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

Product Manufacturer: Pharmasol Corporation, South Easton, MA

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

Mylan Specialty L.P. (a Viatris company) is conducting a 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.