

01 August 2022

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: PRODUCT RECALL OF SPECIFIC BATCHES OF BROMHEXINE HYDROCHLORIDE 8 mg TABLET [PULMOHEX] AND HYOSCINE-N-BUTYLBROMIDE 1 mg/mL (5 mg/5 mL) SYRUP [HYOSPAN]

Drugmakers Laboratories, Inc. is announcing the product recall (Class II) of Bromhexine Hydrochloride 8 mg Tablet [PULMOHEX] and Hyoscine-N-Butylbromide 1 mg/mL (5 mg/5 mL) [Hyospan] until retail level due to non-conformity with Good Manufacturing Practice.

The details of the affected batches are as follows:

DRUG PRODUCT	BROMHEXINE HYDROCHLORIDE 8 mg TABLET [PULMOHEX]		HYOSCINE-N-BUTYLBROMIDE 1 mg/mL (5 mg/5 mL) SYRUP [HYOSPAN]	
REGISTRATION NO.	DRP-5719		DRP-388-01	
BATCH NO./ EXP. DATE	1D146	04/2023	2F119	06/2024
	1D237	05/2023		
	1E202	05/2023		
	1G250	08/2023		
MANUFACTURER	Drugmakers Laboratories, Inc. E & E Industrial Complex, Brgy. San Antonio San Pedro, Laguna			

Drugmakers Laboratories, Inc. is requesting concerned establishments (distributors, sub-distributors, pharmacies, and retailers) to discontinue further distribution, sale, and use of the stated lots. Consumers are also advised not to purchase or use the affected batches.

You may contact us at Telephone Nos. (02) 8556 7965 / (02) 8556-7764 or send an email to csr3@drugmakers.com.ph for any question or additional information regarding the recall.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph or through <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH>.