Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 2021-1688

21 JUN 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Product Recall of Specific Batch of Mupirocin 20 mg/g (2% w/w) Ointment (Mupizee)**

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that the affected batch of the subject product are being recalled from the market. The details of the product are as follows:

DRUG PRODUCT	**MUPIROCIN 20 mg/g (2% w/w) OINTMENT (MUPIZEE)**	
REGISTRATION NO.	**DR-XY46245**	
BATCH NO./EXP. DATE	**820-521**	**11/2022**
MANUFACTURER	**Zee Laboratories Ltd. - Behind 47, Industrial Area, Paonta-Sahib, District Sirmour, Himachal Pradesh, India**	
IMPORTER [MARKETING AUTHORIZATION HOLDER]	**Eon Pharmatek Inc., Unit 703 AIC Burgundy Empire Tower, ADB Ave., Ortigas Center, San Antonio, Pasig City**	

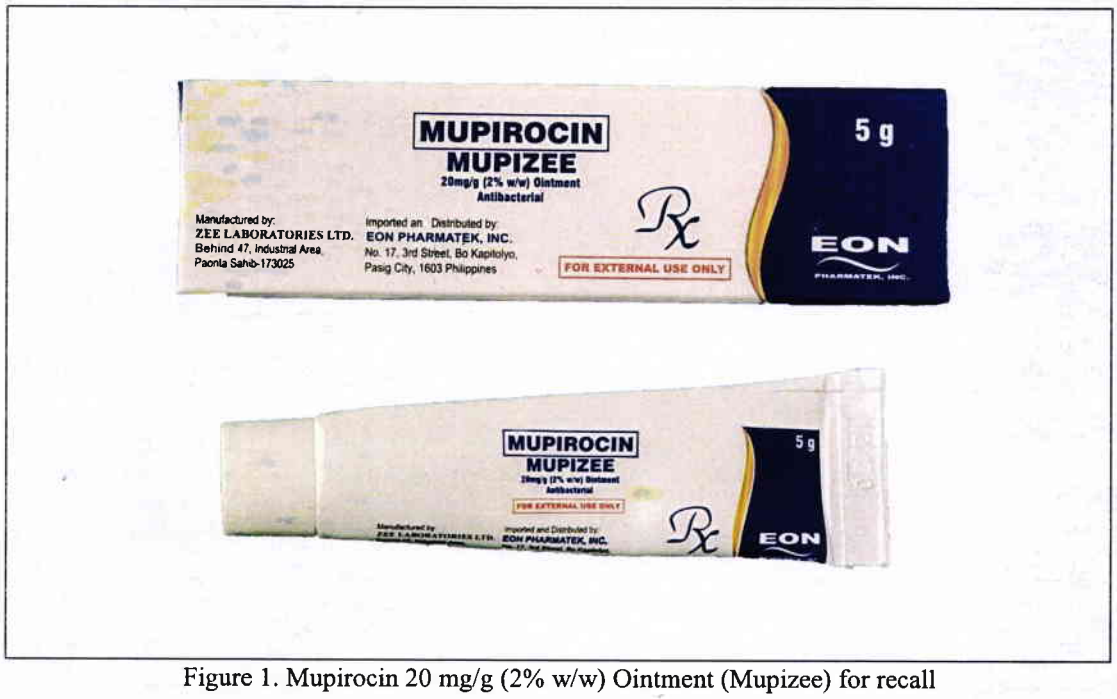

Figure 1. Mupirocin 20 mg/g (2% w/w) Ointment (Mupizee) for recall

Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected batch did not conform to the set specifications of assay test. The assay of a drug product determines the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug. Therefore, the stated batch present quality and efficacy concerns.

Mupirocin is a topical antibacterial agent, active against those organisms responsible for the majority of skin infections. It is used for skin infections, e.g., impetigo, folliculitis, furunculosis in adults, adolescents, children and infants aged 4 weeks and older. Mupirocin 20 mg/g (2% w/w) Ointment (Mupizee) is packed in a collapsible plastic tube.

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batch of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product batch and may contact Eon Pharmatek Inc. by sending an e-mail to **eonpharmaRA@gmail.com** for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batch are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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