



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2016-028**

14 MAR 2016

TO: ALL HEALTHCARE PROFESSIONALS, THE GENERAL PUBLIC AND THE OFFICERS OF THE FIELD REGULATORY OPERATIONS OFFICE

SUBJECT: Product Recall of Batch Number EZ6369 of Rifampicin + Isoniazid + Pyrazinamide + Ethambutol HCl 150 mg/ 75 mg/ 400 mg/ 275 mg Film-Coated Tablet (Onecure)

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that a specific batch of Rifampicin + Isoniazid + Pyrazinamide + Ethambutol HCl 150 mg/ 75 mg/ 400 mg/ 275 mg Film-Coated Tablet (Onecure) is being recalled due to the non-conformance to the specifications of assay and dissolution of the Rifampicin component as reported by the FDA Common Services Laboratory (CSL)-Alabang Testing & Quality Assurance Laboratory. The details of the product batch are as follows:

BRAND NAME	ONECURE
REGISTRATION NUMBER	DRP-1751-01 (IDENTICAL DRUG PRODUCT)
BATCH NUMBER	EZ6369
MANUFACTURING DATE/ EXPIRATION DATE	DECEMBER 2014/ DECEMBER 2016
MANUFACTURER	NOVARTIS (BANGLADESH) LTD. – TONGI, BANGLADESH
IMPORTER	SANDOZ PHILIPPINES CORPORATION – 7/F, ASIAN REINSURANCE BLDG., COR. GAMBOA AND SALCEDO STS., LEGASPI VILLAGE, MAKATI CITY
DISTRIBUTOR (MAH)	THE GENERICS PHARMACY, INC. – 459 QUEZON AVE., QUEZON CITY

Rifampicin + Isoniazid + Pyrazinamide + Ethambutol HCl 150 mg/ 75 mg/ 400 mg/ 275 mg Film-Coated Tablet (Onecure) is used in the management of tuberculosis and



in certain opportunist mycobacterial infections. The product is packed in Blister Pack of 10 Tablets (Box of 60's).

Moreover, the public is also informed that the Principal and Identical Drug Product with the same formulation, indication, manufacturer and importer are also registered with FDA and are subject for recall with the following details:

BRAND NAME	REG. NO.	LOT NO.	EXP. DATE	MAH
RIMSTAR 4 (PRINCIPAL PRODUCT)	DRP-1751	EZ6369	DECEMBER 2016	SANDOZ PHILIPPINES CORPORATION – MAKATI CITY
Unbranded product (IDENTICAL DRUG PRODUCT)	DRP-1751-02			ACTIMED DISTRIBUTIONS, INC. – PARAÑAQUE CITY

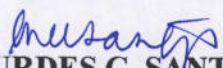
The affected product batch presents safety risk, therapeutic failure, and consequent antimicrobial resistance due to the insufficient amount of Rifampicin present and anticipated problem with the release of the said active pharmaceutical ingredient from the dosage form. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of Rifampicin + Isoniazid + Pyrazinamide + Ethambutol HCl 150 mg/ 75 mg/ 400 mg/ 275 mg Film-Coated Tablet with brand names Onecure, Rimstar 4 and another generic product with Registration No. DRP-1751-02 are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the product batch and may contact The Generics Pharmacy, Inc. at telephone number (02) 821-1111 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batch in the market, appropriately seal discovered stocks of the affected batch of the product, and instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned product batch should be reported immediately to FDA by visiting www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

By Authority of the Secretary of Health


MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General