

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



27 March 2015

FDA Advisory No. 2015 - 014

SUBJECT: PRODUCT RECALL OF ALL LOTS OF ERYTHROMYCIN 40 mg/g (4%) GEL (SANSACNE 4)

The public is hereby warned by the Food and Drug Administration (FDA) that all lots of Erythromycin (Sansacne 4) 40 mg/g (4%) Gel are being recalled from the market. The details of the product are as follows:

REGISTRATION NUMBER	DR-XY17733
LOT NUMBER	ALL LOTS
MANUFACTURER NAME AND ADDRESS	LABORATORIES GALDERMA Z.I. MONTDESIR 74540 ALBY-SUR- CHERAN, FRANCE
IMPORTER	GALDERMA PHILIPPINES, INC. UNIT 3001, ATLANTA CENTRE, #31 ANNAPOLIS ST., SAN JUAN CITY

All lots of Erythromycin (Sansacne 4) 40 mg/g (4%) Gel present safety risks and adverse health consequences as these lots had been determined to not guarantee good quality for the said product.

Erythromycin (Sansacne 4) 40 mg/g (4%) Gel is used for all form of acne of mild to moderate severity. The product is packed in an aluminum tube per 30 g.

The distributors, retailers, hospitals, pharmacies or clinics that have all lots of Erythromycin (Sansacne 4) 40 mg/g (4%) Gel are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected products.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product lots in the market.



Consumers may contact Galderma Philippines, Inc. at telephone no. 725-5444 or mobile no. 0917 827 2049 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of all product lots should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

ATTY. NICOLAS B. LUTERO III, CESO III

OIC-Director IV

Food and Drug Administration