



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**

No. **2016-005**

01 FEB 2016

**SUBJECT: Voluntary Product Recall of Specific Batches of Mupirocin Calcium (as Free Acid) 20 mg/g Cream (Bactroban 2%)**

This is to inform the public that the Marketing Authorization Holder (MAH), GlaxoSmithKline Philippines (GSK), Inc., is voluntarily recalling specific batches of Mupirocin Calcium (as Free Acid) 20 mg/g Cream (Bactroban 2%). This is a precautionary measure to a potential for particulate contamination with glass particles, rust, paint chips and certain fibers from cleaning material and personnel clothing of the Active Pharmaceutical Ingredient (API), Calcium Mupirocin (CaM), as observed by the United States Food and Drug Administration (FDA). The details of the affected thirty-one (31) product batches are as follows:

REGISTRATION NUMBER	<b>DRP-4861</b>	
BATCH NUMBER / EXPIRY DATE	<b>4BC26A / MARCH 2016</b>	<b>5BC06 / AUGUST 2016</b>
	<b>4BC27 / MARCH 2016</b>	<b>5BC07 / AUGUST 2016</b>
	<b>4BC29 / APRIL 2016</b>	<b>5BC08 / AUGUST 2016</b>
	<b>4BC32 / APRIL 2016</b>	<b>5BC10 / AUGUST 2016</b>
	<b>4BC33 / APRIL 2016</b>	<b>5BC11 / SEPTEMBER 2016</b>
	<b>4BC34 / APRIL 2016</b>	<b>5BC12 / SEPTEMBER 2016</b>
	<b>4BC35A / MAY 2016</b>	<b>5BC13 / SEPTEMBER 2016</b>
	<b>4BC36 / MAY 2016</b>	<b>5BC14 / SEPTEMBER 2016</b>
	<b>4BC37 MAY 2016</b>	<b>5BC15A / SEPTEMBER 2016</b>
	<b>4BC38 / MAY 2016</b>	<b>5BC19 / OCTOBER 2016</b>
	<b>4BC39 / MAY 2016</b>	<b>5BC20 / OCTOBER 2016</b>
	<b>4BC42A / JUNE 2016</b>	<b>5BC21 / OCTOBER 2016</b>
	<b>5BC01 / JUNE 2016</b>	<b>5BC22 / NOVEMBER 2016</b>
	<b>5BC02 / JULY 2016</b>	<b>5BC23 / DECEMBER 2016</b>
	<b>5BC03 / JULY 2016</b>	<b>5BC23A / DECEMBER 2016</b>
	<b>5BC04 / JULY 2016</b>	-
MANUFACTURER NAME AND ADDRESS	<b>SMITHKLINE BEECHAM – DON CELSO TUASON AVE., CAINTA, RIZAL</b>	
TRADER (MAH)	<b>GLAXOSMITHKLINE PHILIPPINES, INC. – 2266 CHINO ROCES AVENUE, MAKATI CITY</b>	

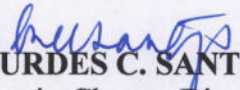


Mupirocin Calcium (as Free Acid) 20 mg/g Cream (Bactroban 2%) is used for the topical treatment of secondarily infected traumatic lesions such as small lacerations, sutured wounds or abrasions. This product is packed in an aluminum tube in 2.5 grams as physician's sample, 5.0 grams and 15.0 grams (export only) in boxes of 1's.

The affected product batches present possibilities of sensitization or local irritation from the presence of the said physical contaminants. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batches of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batches and may contact GSK, Inc. at telephone number +632 864-8516 or mobile number +63 917 8882315 or e-mail us at [info@fda.gov.ph](mailto: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 batches in the market, appropriately seal discovered stocks of the affected batches of the product, and instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA through this link: [www.fda.gov.ph/adr-report-new](http://www.fda.gov.ph/adr-report-new) and fill-out all of the required fields.

  
**MARIA LOURDES C. SANTIAGO, MSc, MM**  
Officer-in-Charge, Director General  
Food and Drug Administration