

May 7, 2018

URGENT: Bracco issues voluntary recall for 1 lot of E-Z-PASTE® Barium Sulfate Esophageal Cream (60% w/w)

Dear ASD Healthcare Customer:

Bracco is conducting a voluntary recall for one lot of E-Z-PASTE® Barium Sulfate Esophageal Cream (60% w/w) due to an out of specification result for a preservative assay, methylparaben, during stability testing on one lot of E-Z-PASTE®. Bracco has no evidence or data to date that suggests patients who received a product from the affected lot would be exposed to any health hazard or adverse event not reported in the approved Prescribing Information of E-Z-PASTE®. The affected lot was distributed from Dec. 21, 2016 to April 12, 2017.

E-Z-PASTE® Barium Sulfate Esophageal Cream (60% w/w), is a barium sulfate cream for oral administration. Each 100 g contains 60 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and, therefore, acts as a positive contrast and agent for radiographic studies.

Bracco provided the following affected lot information:

Product Description	Lot Number	Expiry Dates	NDC
E-Z-Paste Barium Sulfate Esophageal Cream (60% w/w) 454 g / Tube (12 Tubes/case)	00538529	09/30/2018	32909-0770-01

We ask for your cooperation in taking the following action:

- Immediately quarantine inventory of the affected product.
- Return affected lots to:
Stericycle
Event: 8508
2670 Executive Drive, Suite A
Indianapolis, IN 46241

Please contact Stericycle at 1.888.429.7380 (Monday-Friday 8 a.m. to 5 p.m. EST) or Braco8508@stericycle.com if you have any questions or for further information.

For the full recall notice please view the attached documents in the following pages.



URGENT: REVISED DRUG RECALL

E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w)
Lot Number: 00538529
NDC: 32909-770-01

May 7, 2018

Dear Wholesaler:

This is to advise you that Bracco Diagnostics Inc. is expanding the voluntarily recall of E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w) for lot# 00538529 to the **retail level**. The original recall was initiated on March 13, 2018 to the wholesaler and direct accounts levels.

E-Z-PASTE® Barium Sulfate Esophageal Cream (60% w/w) is a barium sulfate cream for oral administration. Each 100 g contains 60 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and, therefore, acts as a positive contrast and agent for radiographic studies. Our records indicate that you may have received shipment of the affected lot.

The lot being recalled is as follows:

NDC Code	Lot Number	Package Size	Manufacture Date	Expiry Date	Dates of Distribution
32909-770-01	00538529	454g / Tube (12 Tubes / case)	10/24/2016	09/30/2018	12/21/2016 to 4/12/2017

This recall action has been initiated due to an out of specification (OOS) result for a preservative assay, methylparaben, during stability testing on one lot of E-Z-PASTE®: 00538529. We have no evidence or data to date that suggests patients who received a product from the affected lot would be exposed to any health hazard or adverse event not reported in the approved Prescribing Information of E-Z-PASTE®.

Product quality is a Bracco priority. We take this matter very seriously and we are committed to ensuring our products meet the highest quality and safety standards. If you have any product from lot # 00538529, please immediately stop using or distributing it, place it under quarantine, and promptly return it with the enclosed shipping label for credit to:

Stericycle
Event Number: 8508
2670 Executive Drive
Suite A
Indianapolis, IN 46241

If you have further distributed any of the affected lot to other wholesale or retail level accounts, please request that they immediately cease distribution of the affected lot. The Trade Team at Bracco will contact you, if not already, to request your customer listing which will be given to Stericycle to complete the recall process with other wholesale or retail level accounts. You will receive a credit memo for the returned goods at Wholesale Acquisition Cost (WAC) per case returned.

Only sealed and unused product should be returned. Please also complete and return the enclosed Business Reply Card even if you have no recalled stock on hand. Do Not return any product lots that are not the subject of this recall.

If you have any questions or for further information, please contact Stericycle at 1-888-429-7380 (Monday - Friday 8 a.m. to 5 p.m. Eastern Time) or Bracco8508@stericycle.com.



LIFE FROM INSIDE

URGENT: REVISED DRUG RECALL

E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w)

Lot Number: 00538529

NDC: 32909-770-01

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation. Bracco expects no inventory disruption to occur as a result of this recall. We sincerely regret any inconvenience and appreciate your cooperation with this matter.

Vice President, Quality and Compliance

8508_04_02AS_V1.1

Bracco Diagnostics Inc.

259 Prospect Plains Road, Bldg. H – Monroe Township, NJ 08831 USA
Telephone: (609) 514-2200 / (800) 631-5245 / Fax: 609-514-2424 / usa.braccoimaging.com