
PharmaTech-LLC
4131 SW 47th Ave Suite 1403
Davie FL 33314
July 15, 2016

URGENT DRUG RECALL

Dear Customer,

This is to inform you of a product recall involving all lots of Diocto Liquid (docusate sodium) 50 mg/mL, NDC 0536-0590-85 manufactured by PharmaTech-LLC and Distributed by Rugby Laboratories. Specific lot numbers and expiration dates are listed below:

PRODUCTS:

Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351407, Exp. Date 09/2016
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351408, Exp. Date 09/2016
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351409, Exp. Date 11/2016
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351410, Exp. Date 12/2016
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351501, Exp. Date 01/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351502 Exp. Date 01/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351503 Exp. Date 03/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot# 20351504 Exp. Date 04/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351505 Exp. Date 05/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351506 Exp. Date 06/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351507 Exp. Date 06/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351508 Exp. Date 07/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351509 Exp. Date 10/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351510 Exp. Date 10/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351511 Exp. Date 11/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351512 Exp. Date 11/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351513 Exp. Date 11/2017
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351601 Exp. Date 01/2018
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351602 Exp. Date 02/2018
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351603 Exp. Date 03/2018
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351604 Exp. Date 04/2018
Diocto Liquid, Docusate Sodium 50 mg/5 mL, NDC 0536-0590-85, Lot#20351605 Exp. Date 04/2018



PharmaTech, LLC of Davie Florida is voluntarily recalling the above product lots in the interest of public safety after it was discovered that some bottles may be adulterated with *Burkholderia cepacia*.

Potentially affected lots listed in this recall began shipping on 09/22/2014. Use of docusate sodium liquid contaminated with *B. cepacia* may result in serious infections that could be life-threatening in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis

At this time no other products or lots are affected.

DEPTH OF THE RECALL:

This recall is being carried out to the retail level. Your assistance is appreciated and necessary to prevent patient harm.

INSTRUCTIONS TO CUSTOMERS:

1. Stop distributing and quarantine these affected products immediately.
2. Please carry out a physical count and record the needed information on the Business Reply Form which is included with this letter.
3. Fax the Business Reply Form to (954)-583-8778 attention Angelina Raybrun, Recall Coordinator within ten business days, even if you do not have the recalled products in stock.
4. Once a RMA is obtained from PharmaTech, LLC please return the recalled product to the address below using the shipping method specified in the form:

PharmaTech-LLC
4131 SW 47th Ave, Suite 1403
Davie FL 33314

5. If you have further distributed the affected products please notify your Retail/Wholesale customer immediately and have them return the product back to you. Follow the instructions in this letter to obtain any additional RMA's needed for distributed products.



Your timely response to the recall notification is requested Thank you.

Please fill out and fax this reply within 10 business days, even if you do not have the recalled product.

Please complete and fax to: PharmaTech-LLC at: Fax (954) 583-8778.

Customer Name: _____

Street Address: _____

City: _____

Contact Name: _____

Email, Phone & Fax: _____

Signature: _____ Date: _____

For questions please contact:

Angelina Raybrun
Recall Coordinator, PharmaTech, LLC

Primary contact number: (754) 701-8320
Secondary Contact number: (954) 581-7881 x 6030
Email Address: recall@pharmatech-llc.com



Other Information

This recall is being carried out to the RETAIL LEVEL and is only for the specific products / lots listed above. No other lots, packages, or formulations are being recalled.

For questions regarding returns, please contact PharmaTech-LLC Angelina Raybrun, Recall Coordinator,

For all other questions please contact Rugby Laboratories at 1-800-645-2158

To ensure proper credit please return recalled products to PharmaTech-LLC no later than September 15, 2016.

Any product returned in addition or in lieu of recalled product will be destroyed, without issuance of a credit.

Thanks

Angelina Raybrun
Recall Coordinator, PharmaTech, LLC

See enclosed product photograph for ease in identifying the product.

