COMPANY ANNOUNCEMENT

Pfizer Inc. Issues a Voluntary Nationwide Recall for 2 Lots of RELPAX® (eletriptan hydrobromide) 40 mg Tablets Due to Potential Microbiological Contamination of Non-Sterile Products

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

August 14, 2019

FDA Publish Date:

August 15, 2019

Product Type:

Drugs

Reason for Announcement:

Microbiological Contamination

Company Name:

Pfizer Inc

Brand Name:

RELPAX

Product Description:

RELPAX® (eletriptan hydrobromide) 40 mg tablets

Company Announcement

Pfizer Inc. is voluntarily recalling RELPAX® (eletriptan hydrobromide) 40 mg tablets, lots AR5407 and CD4565, to the Patient level. Pfizer Inc. initiated this recall because these product lots may not meet Pfizer's in-house microbiological specification for the potential presence of Genus Pseudomonas and Burkholderia.

Individuals who consume oral products contaminated with microorganisms are at risk of bacterial dissemination from the gut to the bloodstream potentially resulting in serious, life-threatening infections. In addition, there is risk of temporary gastrointestinal distress without serious infection. For the general population these risks are low; for certain vulnerable patient populations (such as patients with compromised immune systems, cystic fibrosis and chronic granulomatous disease) there may be the potential for serious adverse events including life-threatening infections. To date, Pfizer has not received any customer complaints or reports of adverse events related to this issue.

RELPAX®(eletriptan hydrobromide) is indicated for the acute treatment of migraine with or without aura in adults.

RELPAX ® (eletriptan hydrobromide) 40 mg tablets are packaged in cartons as indicated below. The affected lots were distributed nationwide to wholesalers, retailers, hospitals, and healthcare providers in the United States and Puerto Rico from June 2019, to July 2019.

Carton NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0049-2340-45	AR5407	2022 FEB	40 mg	Carton containing 6 tablets (1 blister card x 6 tablets)
0049-2340-05	CD4565	2022 FEB	40 mg	Carton containing 12 tablets (2 blister cards x 6 tablets)

Pfizer Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Pfizer Inc. has notified its direct customers via a recall letter to arrange for return of any recalled product.

Anyone with an existing inventory of the lots, which are being recalled, should stop use and distribution and quarantine immediately. Inform healthcare professionals in your organization of this recall. For retailers, hospitals, or healthcare providers that have dispensed product to patients, please notify these patients regarding the recall. For additional assistance, call Stericycle at 877-225-9750 (Monday through Friday, 8 a.m. to 5 p.m. ET).

For clinical inquiries, please contact Pfizer using the below information.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Monday through Friday 9am to 5pm ET)	For medical questions regarding this product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

Patients who are taking this product should consult with their healthcare provider or pharmacy to determine if they have the

affected product lots. Patients with the affected lots should return the product to their pharmacy or contact Stericycle Inc. at 877-225-9750 for instructions on how to return their product and obtain reimbursement for their cost.

If you have received free product through the Pfizer Patient Assistance Program (PAP) or the Pfizer Institutional Patient Assistance Program (IPAP), please check if you have received any of the affected product lots above. If you have any of the affected product lots in your possession, please contact your healthcare provider to return the product to them.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/node/360543)
- Regular Mail or Fax: Download form (/node/360547) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Stericycle

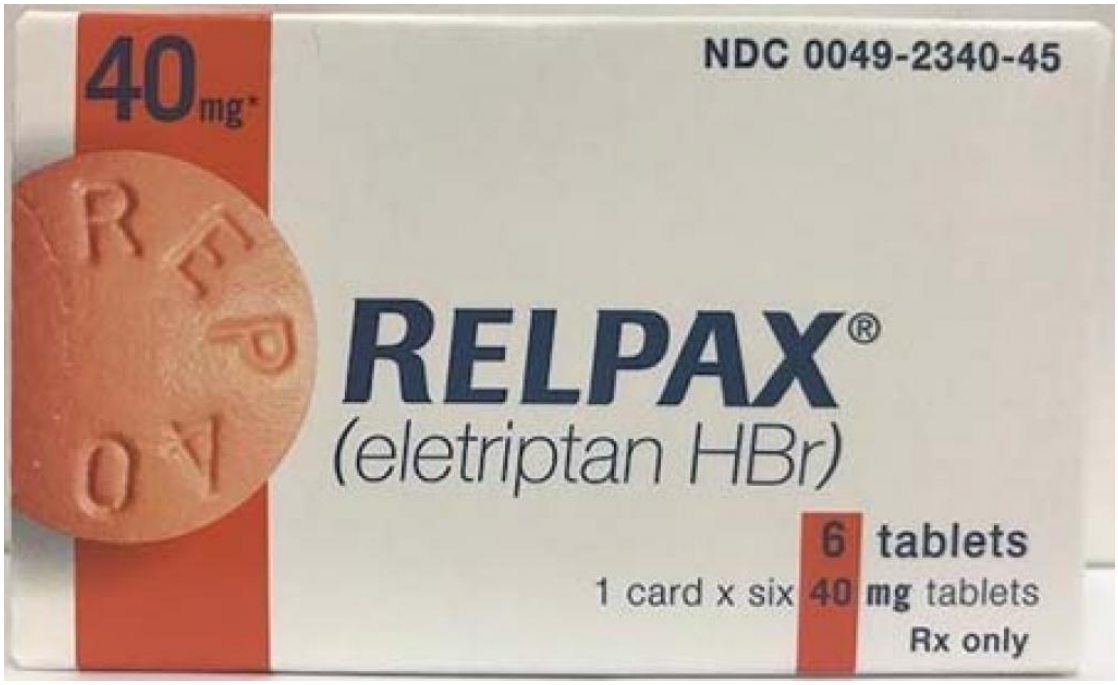
877-225-9750

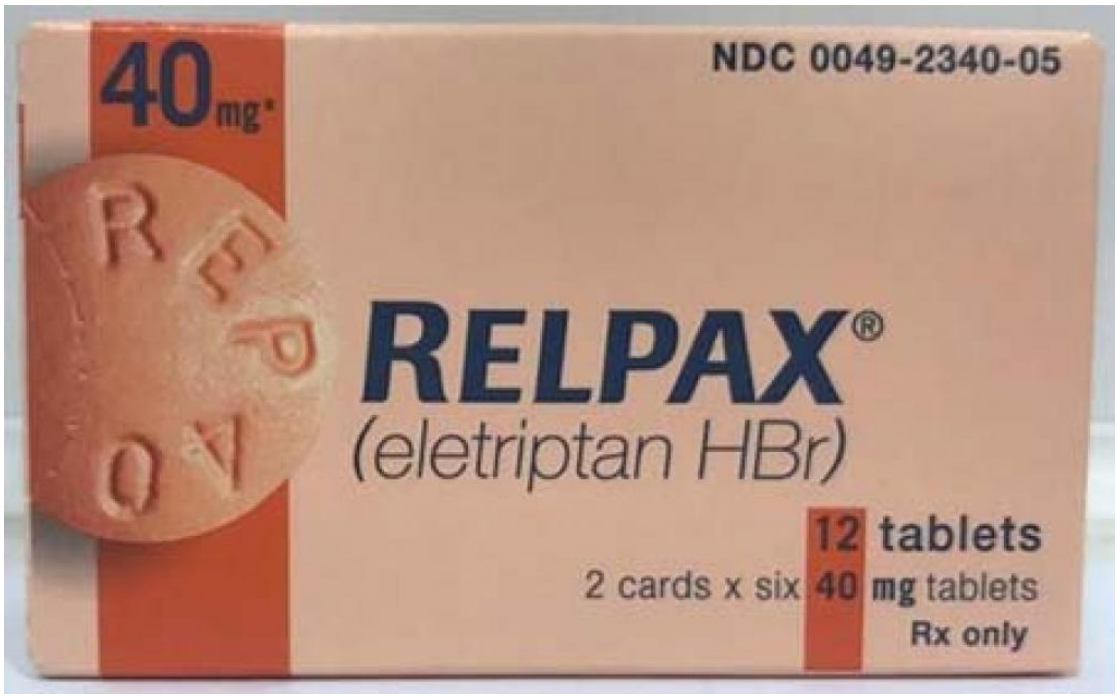
Media:

610-329-1340

Kim.bencker@pfizer.com (mailto:Kim.bencker@pfizer.com)

Product Photos





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