

Pfizer – Recall of Relpax® (eletriptan)

- On August 14, 2019, Pfizer announced a voluntary patient-level recall of two lots of Relpax (eletriptan) 40 mg tablets because these product lots may not meet Pfizer’s in-house microbiological specification for the potential presence of genus *Pseudomonas* and *Burkholderia*.
- Relpax tablets are packaged in cartons as indicated below. The affected lots were distributed nationwide to wholesalers, retailers, hospitals, and healthcare providers in the U.S. and Puerto Rico from June 2019 to July 2019.

Product Description	NDC#	Lot# (Expiration Date)	Configuration/ Count
Relpax (eletriptan hydrobromide) 40 mg tablets	0049-2340-45	AR5407 (2/2022)	Carton containing 6 tablets (1 blister card x 6 tablets)
	0049-2340-05	CD4565 (2/2022)	Carton containing 12 tablets (2 blister cards x 6 tablets)

- Relpax is indicated for the acute treatment of migraine with or without aura in adults.
- 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.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Relpax tablets.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- For more information regarding this recall, contact Pfizer at **1-800-438-1985** or Stericycle (appointed company for Pfizer) at **1-877-225-9750**.