August 19, 2019

COM-2019-037

Recall: Voluntary Nationwide Recall of RELPAX® (eletriptan hydrobromide) 40 mg Tablets

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on August 15, 2019, the US Food and Drug Administration (FDA) issued a statement notifying that Pfizer Inc. is recalling to the patient level, 2 lots of RELPAX® (eletriptan hydrobromide) 40 mg tablets because of potential non-compliance with microbiological parameters for Genus Pseudomonas and Burkholderia. RELPAX® (eletriptan hydrobromide) is indicated for the acute treatment of migraine with or without aura in adults. The affected lots by the recall are detailed in Table 1.

Table 1: Affected Product of RELPAX® 40mg tablets

NDC	Product	Count	Affected Lot	Expiration date
0049-2340-45	RELPAX® 40mg	Carton containing 6 tablets (1 blister card x 6 tablets)	AR5407	2022 FEB
0049-2340-05	RELPAX® 40mg	Carton containing 12 tablets (2 blister cards x 6 tablets)	CD4565	2022 FEB

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advise them to return the product to the pharmacy or contact Stericycle Inc. at 877-225-9750 (Monday through Friday, 8 a.m. to 5 p.m. ET) for instructions on how to return their product and obtain reimbursement for their cost.
3. For clinical inquiries, contact Pfizer at:
    a. Pfizer Medical Information - 800-438-1985, option 3, (Monday through Friday 9am to 5pm ET)
    b. Pfizer Drug Safety - 800-438-1985, option 1 (24 hours a day 7 days per week)

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-inc-issues-voluntary-nationwide-recall-2-lots-relpaxr-eletriptan-hydrobromide-40-mg-tablets

Clinical Department

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com