

December 24, 2019

COM-2019-054

Voluntary Nationwide Recall of Levetiracetam Oral Solution, 100mg/Ml

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 December 18, 2019, the U.S. Food and Drug Administration (FDA) issued a statement that Lannett Company, Inc. is recalling two (2) lots of Levetiracetam Oral Solution, 100mg/mL due to microbial contamination with *Bacillus subtilis*. Infections may occur in patients. The affected lots are detailed in following table.

Table 1: Affected Products of Levetiracetam

| NDC | Description | Lot | Expiration date Range |
|---|--------------|-------|--------------------------|
| Levetiracetam Oral Solution 100mg/mL | 54838-548-80 | 2190A | 07/2021 |
| Levetiracetam Oral Solution 100mg/mL | 54838-548-80 | 2191A | 07/2021 |

The Pharmacy must:

 Identify if they have the product in inventory and immediately stop using and dispensing the it. Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.





- 2. Consumers: questions regarding this recall, refer to the following contact information:
 - Phone: (866) 255-4983 Monday-Friday, 9:00 a.m. 5:00 p.m. (EST)
 - Medical questions: Phone: (844) 834-0530 Monday-Friday, 9:00a.m. 5:00 p.m. (EST).

Remember that any adverse event related to this or any other pharmaceutical product can be Page | 2 reported to the FDA's MedWatch Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

For additional information visit:

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lannett-issues-voluntarynationwide-recall-levetiracetam-oral-solution-100mgml-due-microbial

Clinical Department

