

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:**

1. Identify if they have the product in inventory and immediately stop using and dispensing 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 reported to the FDA's MedWatch Adverse Event Reporting program:**

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- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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-voluntary-nationwide-recall-levetiracetam-oral-solution-100mgml-due-microbial>

**Clinical Department**



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