

Taro Pharmaceuticals - Recall of phenytoin

- On February 21, 2020, <u>Taro Pharmaceuticals announced</u> a voluntary, consumer-level recall of two lots of <u>phenytoin</u> oral suspension because product may not re-suspend when shaken, as instructed for administration, which could result in under or overdosing.
- The recalled lot 327874 of phenytoin was distributed in the U.S. between May 3 and July 5, 2019, and the recalled lot 327876 of phenytoin was distributed between July 1 and August 21, 2019.

| Product Description | NDC# | Lot# (Expiration Date) |
|---|--------------|---|
| Phenytoin 125 mg/5 mL oral suspension, 237 mL bottles | 51672-4069-1 | 327874 (December 2020); 327876 (December 2020) |

- Phenytoin oral suspension is indicated for the treatment of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures.
- The population at risk is primarily infants and young children. In those patients, there is a reasonable probability that inaccurate dosing might result in a serious adverse effect such as intoxication or breakthrough seizures requiring medical intervention.
- For a small minority of patients, who might have severe or repeated breakthrough seizures, a drop in their phenytoin blood levels could result in life-threatening status epilepticus requiring immediate emergency room treatment.
- To date, Taro has not received any adverse event reports related to this recall.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled phenytoin.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Consumers with questions regarding this recall can contact Taro by calling **1-866-705-1553** or by email at **TaroPVUS@taro.com**.



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