Taro Pharmaceuticals – Recall of phenytoin

- On February 21, 2020, Taro Pharmaceuticals announced a voluntary, consumer-level recall of two lots of phenytoin 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 e-mail at **TaroPVUS@taro.com**.