RXADVANCE
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Phenytoin Oral Suspension Recall Alert

Date of Notice: 02/20/2020

Brief Description of Recall

On February 20, 2020, Taro Pharmaceuticals USA, Inc. issued a voluntary recall on two lots of phenytoin oral suspension 125mg/5ml due to suspension issues that may result in under- or over-dosing.

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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Phenytoin oral suspension, 125mg/5ml	51672-4069-1	327874 327876	12/2020

Prescriber Information

Taro has not received any adverse event reports related to this recall.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form 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

Member Information

Members with questions regarding this recall can contact Taro by calling 1-855-536-6300 or by e-mail at TaroPVUS@taro.com, Monday through Friday between 7:00 am and 7:00 pm, U.S. Central Time.

Members should contact their prescriber if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.