CarePlus HEALTH PLANS

Drug recall notice for Taro Pharmaceuticals phenytoin oral suspension

To assist you in the care of your patients, we would like to alert you to the recall of two lots of Taro Pharmaceuticals phenytoin oral suspension USP, 125 mg/5 mL, both in 237 mL bottles, on Feb. 20, 2020.[1,2] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall. We have listed alternative options below.

Taro voluntarily recalled these lots of phenytoin oral suspension because the product may not re-suspend when shaken, as instructed for administration, which could result in under- or overdosing. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

The population at risk of adverse effects is primarily infants and young children. In those patients, inaccurate dosing might result in serious adverse effects, 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 reports of adverse events related to use of the product as part of this recall.

Medications included in this recall:

Product name	NDC number	Lot number	Expiration date
phenytoin oral suspension 125 mg/5 mL	51672-4069-1	327874	December 2020
phenytoin oral suspension 125 mg/5 mL	51672-4069-1	327876	December 2020

Recommendations:

Preferred formulary alternatives for CarePlus members:

Medication	Manufacturer	NDC number
phenytoin 125 mg/5 mL suspension	Greenstone LLC	59762-0531
phenytoin 125 mg/5 mL suspension	Morton Grove Pharmaceuticals Inc.	60432-0131
phenytoin 125 mg/5 mL suspension	VistaPharm Inc.	66689-0036
phenytoin 125 mg/5 mL suspension	VistaPharm Inc.	66689-0775

To search for other medications that your patient's CarePlus plan covers, you can access the plan's drug lists at **www.CarePlusHealthPlans.com/medicare-plans/2020-prescription-drug-guides**.

Information for providers:[1,2]

- We have sent a letter to your patients who have had a claim for Taro phenytoin oral suspension and asked them to contact their physicians or healthcare providers if their medication is included in the recall and if they have experienced problems that may be related to using these drug products.
- Healthcare providers with questions can contact Taro by calling 1-866-705-1553 or by email at TaroPVUS@taro.com, Monday through Friday, from 7 a.m. to 7 p.m., Central time.
- Patients may report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
    - **Online:** Complete and submit the report.
        - Select "Consumer/Patient (FDA Form 3500B)."
    - **Regular mail or fax:** Download the form.
        - Select "Form FDA 3500B – Voluntary Reporting for Consumers" and submit by mail to the address on the form or by fax to 1-800-FDA-0178.

References:

1. "Taro Pharmaceuticals U.S.A. Issues Voluntary Nationwide Recall of Phenytoin Oral Suspension USP, 125 mg/5ml Due to Possible Underdosing or Overdosing." U.S. Food and Drug Administration. Feb. 21, 2020. www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall-phenytoin-oral-suspension-usp-125-mg5ml

2. "Taro Pharmaceuticals U.S.A. Issues Voluntary Nationwide Recall of Phenytoin Oral Suspension USP, 125 mg/5 mL Due to Possible Underdosing or Overdosing." Taro Pharmaceutical Industries Ltd. Feb. 20, 2020. https://taro.gcs-web.com/news-releases/news-release-details/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall