Drug recall notice for NP Thyroid tablets

To assist you in the care of your patients, we would like to alert you to the recall of certain lots of NP Thyroid® tablets, manufactured by Acella Pharmaceuticals.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

Background:

On **April 30, 2021**, Acella Pharmaceuticals voluntarily recalled 38 lots of NP Thyroid® (thyroid tablets, USP), in 100- and 7-count bottles, because testing found these lots to be subpotent. The product may have as low as 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4). Patients who receive these subpotent drugs may experience signs and symptoms of hypothyroidism (underactive thyroid), which may include fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland, and/or unexplained weight gain or difficulty losing weight. There is reasonable risk of serious injury to newborn infants or pregnant women with hypothyroidism, including early miscarriage, fetal hyperthyroidism, and/or impairments to fetal neural and skeletal development. In elderly patients and patients with underlying cardiac disease, toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia. To date, Acella has received 43 reports of serious adverse events that could possibly be related to this recall.

Medications included in this recall:

Visit the FDA website for specific details about the recalled medications.

Recommendations:

To reduce impact to your patients, encourage them to contact their pharmacy to obtain a non-impacted alternative supply.

- 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/2021-prescription-drug-guides

Information for providers:[1]

- We have sent a letter to your patients who have had a claim for NP Thyroid 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 Acella customer service at 888-280-2044, Monday – Friday, 8 a.m. – 5 p.m., Eastern time; or email recall@acellapharma.com.
- Patients may report adverse reactions or quality problems experienced with the use of this product to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program 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 800-FDA-0178.

Reference:

1. "Acella Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Certain Lots of NP Thyroid® (Thyroid Tablets, USP) Due to Sub Potency." U.S. Food and Drug Administration. April 30, 2021. www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-certain-lots-np-thyroidr-thyroid-0?utm_medium=email&utm_source=govdelivery