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.[1,2] 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, where applicable.

Background:

On **May 22, 2020**, Acella Pharmaceuticals voluntarily recalled 13 lots of 30 mg, 60 mg and 90 mg NP Thyroid (thyroid tablets, USP), packaged in 100-count bottles, because testing found these lots to be *super potent*—i.e., contain up to 115% of the labeled amount of liothyronine (T3). NP Thyroid contains levothyroxine and liothyronine, which treat hypothyroidism (underactive thyroid). Patients who receive super-potent NP Thyroid may experience signs and symptoms of hyperthyroidism (overactive thyroid), which include but are not limited to weight loss, heat intolerance, fatigue, muscle weakness, hypertension, chest pain, rapid heart rate or heart rhythm disturbances. Pregnant women also may experience negative maternal and fetal outcomes, including miscarriage and/or impairment to fetal development. To date, Acella has received two reports of adverse events related to this recall.

On **Sept. 17, 2020**, Acella Pharmaceuticals further announced that one lot of 15 mg and one lot of 120 mg NP Thyroid (thyroid tablets, USP) are being recalled because testing has found these lots to be *subpotent*. The product may have as low as 87% of the labeled amount of levothyroxine (T4). Patients who receive these subpotent drugs may experience signs and symptoms of hypothyroidism, 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 four reports of adverse events for these lot numbers possibly related to this recall.

Medications included in this recall:

Product name	NDC number	Lot number	Expiration date
NP Thyroid 15 mg	42192-0327-01	M327E19-1	October 2020
NP Thyroid 30 mg	42192-0329-01	M329A19-1	12/20/2020
NP Thyroid 30 mg	42192-0329-01	M329H18-1	07/20/2020

NP Thyroid 30 mg	42192-0329-01	M329J18-1	08/20/2020
NP Thyroid 30 mg	42192-0329-01	M329J18-2	08/20/2020
NP Thyroid 30 mg	42192-0329-01	M329J18-3	08/20/2020
NP Thyroid 30 mg	42192-0329-01	M329M18-2	11/20/2020
NP Thyroid 60 mg	42192-0330-01	M330J18-2A	08/20/2020
NP Thyroid 60 mg	42192-0330-01	M330J18-3	08/20/2020
NP Thyroid 90 mg	42192-0331-01	M331G18-1	06/20/2020
NP Thyroid 90 mg	42192-0331-01	M331J18-1	08/20/2020
NP Thyroid 120 mg	42192-0328-01	M328F19-3	November 2020

Recommendations:

To reduce impact to your patients, please consider the listed alternative options below.

Preferred alternatives
levothyroxine tablets (all strengths)
liothyronine tablets (all strengths)

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]

- 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.

References:

1. "Acella Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Certain Lots of NP Thyroid® (Thyroid Tablets, USP) Due to Super Potency." U.S. Food and Drug Administration. May 22, 2020. www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-certain-lots-np-thyroidr-thyroid
2. "Acella Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Two Lots of NP Thyroid®, Thyroid Tablets, USP Due to Sub Potency." U.S. Food and Drug Administration. Sept. 17, 2020. www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-two-lots-np-thyroidr-thyroid-tablets