RXADVANCE
2 Park Central Drive
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NP Thyroid Recall Alert

Date of Notice: 05/22/2020

Brief Description of Recall Alert

On May 22, 2020 Acella Pharmaceuticals, LLC voluntarily recalled a total of 13 lots of 30-mg, 60-mg and 90-mg NP Thyroid® (thyroid tablets, USP). The FDA testing has found these lots to be super potent. The product may have up to 115.0% of the labeled amount of Liothyronine (T3).

Members being treated for hypothyroidism (underactive thyroid), 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 who take super potent NP Thyroid may also experience negative maternal and fetal outcomes including miscarriage and/or impairment to fetal development.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
NP Thyroid 30 mg	42192-329-01	M329A19-1	12/2020
NP Thyroid 30 mg	42192-329-01	M329H18-1	07/2020
NP Thyroid 30 mg	42192-329-01	M329J18-1	08/2020
NP Thyroid 30 mg	42192-329-01	M329J18-2	08/2020
NP Thyroid 30 mg	42192-329-01	M329J18-3	08/2020
NP Thyroid 30 mg	42192-329-01	M329M18-2	11/2020
NP Thyroid 60 mg	42192-330-01	M330J18-2A	08/2020
NP Thyroid 60 mg	42192-330-01	M330J18-3	08/2020
NP Thyroid 90 mg	42192-331-01	M331G18-1	06/2020
NP Thyroid 90 mg	42192-331-01	M331J18-1	08/2020
NP Thyroid 90 mg	42192-331-01	M331J18-2	08/2020
NP Thyroid 90 mg	42192-331-01	M331M18-1	11/2020
NP Thyroid 90 mg	42192-331-01	M331M18-2	11/2020

Prescriber Information

To date, Acella has received two reports of adverse events known to be 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

Acella is proactively notifying its wholesalers by email and phone to discontinue distribution of the product being recalled and is arranging for return of all recalled products. Patients who are currently taking NP Thyroid from the lots being recalled should not discontinue use without contacting their healthcare provider for further guidance and/or a replacement prescription.

Consumers with questions about the recall can email Acella Pharmaceuticals at recall@acellapharma.com or contact Acella Customer Service at 1-800-541-4802, Monday through Thursday from 9:00 am to 5:00 pm ET and Friday from 9:00 am to 12:30 pm ET. Consumers should contact their physician or healthcare provider 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 those impacted by this recall.