RXADVANCE
2 Park Central Drive
Southborough, MA 01772

NP Thyroid® Recall Alert

Date of Notice: 09/17/2020

Brief Description of Recall Alert

Acella Pharmaceuticals, LLC is voluntarily recalling one lot of 15-mg and one lot of 120-mg NP Thyroid®, Thyroid Tablets, USP [levothyroxine (T4) and liothyronine (T3)] to the consumer level. The products are being recalled because testing has found these lots to be sub potent. The product may have as low as 87% of the labeled amount of levothyroxine (T4). More information can be found at www.npthyroid.com/product-updates.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
NP Thyroid® 15, Thyroid Tablets, USP, 0.25 grain (15 mg)	42192-327-01	M327E19-1	10/2020
NP Thyroid® 120, Thyroid Tablets, USP, 2.0 grain (120 mg)	42192-328-01	M328F19-3	11/2020

Prescriber Information

To best identify the product, the NDCs, Product Description, Lot Numbers, and Expiration Dates are listed. These lots were distributed nationwide in the USA to Acella's direct accounts, including wholesalers, pharmacies, and healthcare offices. Additionally, consumers may be able to determine that their product is not impacted by the recall if the "use by," "discard after," or "expiration date" on their prescription bottle is on or after December 2020.

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 two above referenced lots 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 our representatives at 1-888-280-2044, Monday through Friday from 8:00 am to 5:00 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 has provided education on this recall alert in this notification.