

COMPANY ANNOUNCEMENT

Acella Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Certain Lots of NP Thyroid® (Thyroid Tablets, USP) Due to Super Potency

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

May 22, 2020

FDA Publish Date:

May 22, 2020

Product Type:

Drugs

Reason for Announcement:

Super potency

Company Name:

Acella Pharmaceuticals, LLC

Brand Name:

Acella

Product Description:

30-mg, 60-mg and 90-mg NP Thyroid®

Company Announcement

Acella Pharmaceuticals, LLC is voluntarily recalling a total of 13 lots of 30-mg, 60-mg and 90-mg NP Thyroid® (thyroid tablets, USP) to the consumer level. The products are being recalled because our testing has found these lots to be superpotent. The product may have up to 115.0% of the labeled amount of Liothyronine (T3).

Risk Statement: Patients being treated for hypothyroidism (underactive thyroid), who receive superpotent 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 superpotent NP Thyroid may also experience negative maternal and fetal outcomes including miscarriage and/or impairment to fetal development. Patients should talk to their healthcare professional before they stop taking their NP Thyroid medicine. To date, Acella has received two reports of adverse events known to be related to this recall.

NP Thyroid (thyroid tablets, USP) is composed of levothyroxine and liothyronine, and used to treat hypothyroidism (underactive thyroid). The products subject to recall are packed in 100-count bottles. See product images.

To best identify the product, the NDC's, Product Description, Lot Numbers and Expiration Dates are listed. These lots were distributed nationwide in the USA to Acella's direct accounts.

Product	NDC	Lot #	Exp. Date
NP Thyroid 30 mg	42192-329-01	M329A19-1	20-Dec
		M329H18-1	20-Jul
		M329J18-1	20-Aug
		M329J18-2	20-Aug
		M329J18-3	20-Aug
		M329M18-2	20-Nov
NP Thyroid 60 mg	42192-330-01	M330J18-2A	20-Aug
		M330J18-3	20-Aug

Product	NDC	Lot #	Exp. Date
NP Thyroid 90 mg	42192-331-01	M331G18-1	20-Jun
		M331J18-1	20-Aug
		M331J18-2	20-Aug
		M331M18-1	20-Nov
		M331M18-2	20-Nov

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 (mailto: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.

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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

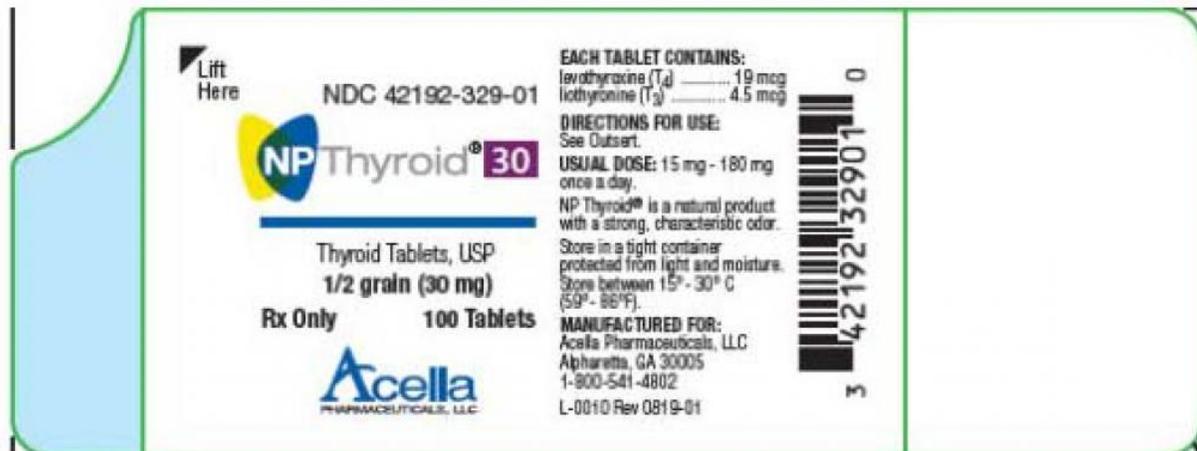
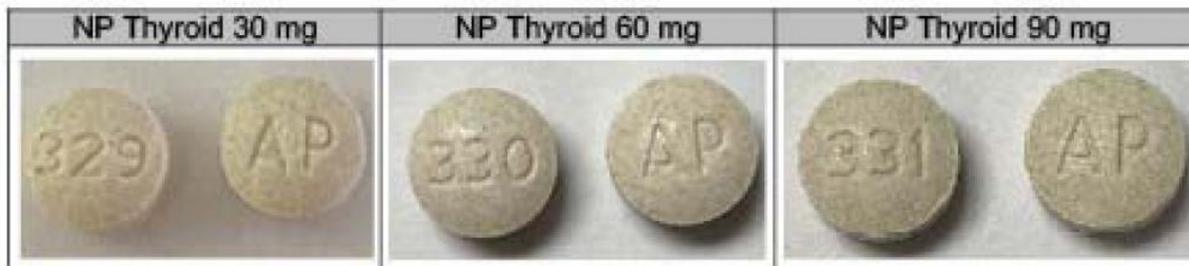
Company Contact Information

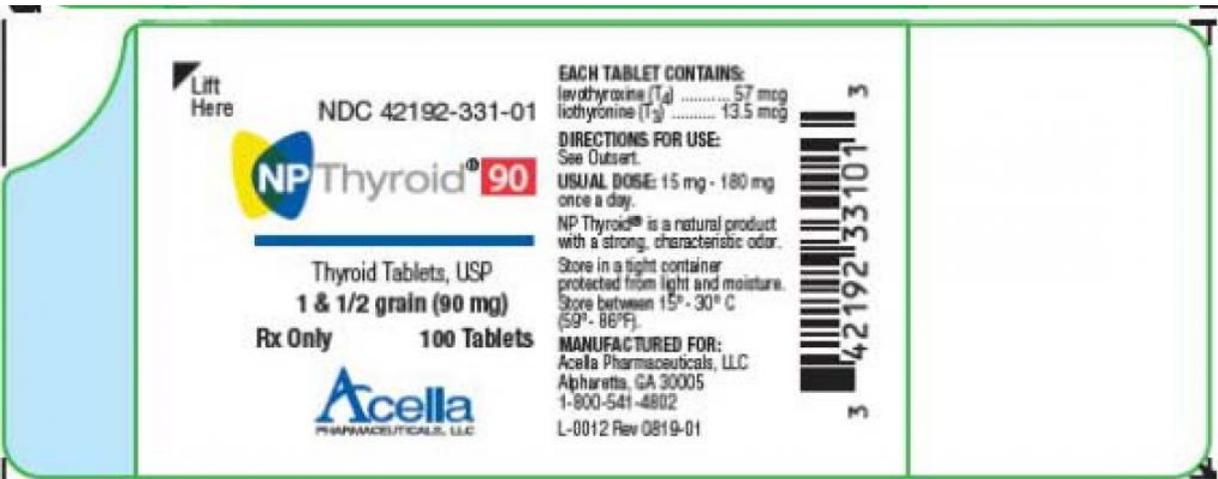
Consumers:

Allen Fields, Senior Vice President, Clinical and Regulatory Affairs

☎ 1-800-541-4802

Product Photos





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