RXADVANCE
136 Turnpike Road
Southborough, MA 01772

NP Thyroid® Recall Alert

Date of Notice: 04/30/2021

Brief Description of Safety Alert

Acella Pharmaceuticals, LLC, is voluntarily recalling certain lots of 15 mg, 30 mg, 60 mg, 90 mg and 120 mg NP Thyroid®, Thyroid Tablets, USP [levothyroxine (T4) and liothyronine (T3)]. The products are being recalled because routine testing has found these lots to be subpotent. The product contains less than 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4).

Patients being treated for hypothyroidism (underactive thyroid), who receive subpotent NP Thyroid®, 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 in 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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
NP Thyroid® 15mg Tablets	42192-327-01	M327L19-1	4/30/2021
NP Thyroid® 15mg Tablets	42192-327-01	M327H19-3A	7/31/2021
NP Thyroid® 15mg Tablets	42192-327-01	M327D20-1 M327D20-3	3/31/2022
NP Thyroid® 30mg Tablets	42192-329-01	M329D20-1 M329D20-2 M329D20-3 M330D20-1 M330D20-2	3/31/2022
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-2A M330J19-4A M330J19-5A M330J19-6A M330J19-7A M330J19-9A	8/31/2021
NP Thyroid® 60mg Tablets	42192-330-01	M330K19-10 M330K19-1A M330K19-9	9/30/2021

NP Thyroid® 90mg Tablets	42192-331-01	M331J19-10A M331J19-11 M331J19-2A M331J19-6A M331K19-1 M331K19-2 M331K19-6	8/31/2021
NP Thyroid® 120mg Tablets	42192-328-01	M328H19-2B M328J19-11 M328J19-2A M328J19-3A M328J19-4A M328J19-5A M328J19-6A M328J19-7A M328J19-9B	8/31/2021
NP Thyroid® 120mg Tablets	42192-328-01	M328K19-2 M328K19-4A	9/30/2021

Prescriber Information

Acella is proactively notifying its consignees to discontinue distribution of the above referenced lots being recalled and is arranging for return of all recalled products. To date, Acella has received 43 reports of serious adverse events that could possibly 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

Members with questions about the recall can email Acella Pharmaceuticals at recall@acellapharma.com or contact our representatives at 1-888-424-4341, Monday through Friday from 8:00 am – 5:00 pm ET. Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members 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.

RxAdvance Response

RxAdvance recommends that you speak to your doctor or healthcare provider about concerns regarding this recall.