

Acella Pharmaceuticals – Recall of NP Thyroid® (thyroid)

- On April 29, 2021, <u>Acella Pharmaceuticals announced</u> a voluntary, consumer-level recall of 35 lots of 15 mg, 30 mg, 60 mg, 90 mg and 120 mg <u>NP Thyroid (thyroid)</u> tablets because testing has found these lots to be subpotent. The products contain less than 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4).
- The recalled NP Thyroid tablets were distributed in the U.S. between March 4, 2020 and March 16, 2021.

Product Description	NDC#	Lot# (Expiration Date)
NP Thyroid 30 mg tablet	42192032901	M329D20-2 (03/31/22);
		M329D20-3 (03/31/22);
		M329D20-1 (03/31/22)
NP Thyroid 90 mg tablet	42192033101	M331K19-1 (09/30/21);
		M331K19-2 (09/30/21);
		M331J19-6A (08/31/21);
		M331J19-2A (08/31/21);
		M331J19-11 (08/31/21);
		M331J19-10A (08/31/21);
		M331K19-6 (09/30/21)
NP Thyroid 60 mg tablet	42192033001	M330K19-10 (09/30/21);
		M330D20-1 (03/31/22);
		M330D20-2 (03/31/22);
		M330J19-2A (08/31/21);
		M330J19-4A (08/31/21);
		M330J19-5A (08/31/21);
		M330J19-6A (08/31/21);
		M330K19-1A (09/30/21);
		M330K19-9 (09/30/21);
		M330J19-9A (08/31/21);
		M330J19-7A (08/31/21)
NP Thyroid 15 mg tablet	42192032701	M327D20-1 (03/31/22);
		M327D20-3 (03/31/22);
		M327H19-3A (07/31/21);
		M327L19-1 (04/30/21)
NP Thyroid 120 mg tablet	42192032801	M328H19-2B (08/31/21);
		M328K19-2 (09/30/21);
		M328J19-7A (08/31/21);
		M328J19-6A (08/31/21);

M328J19-5A (08/31/21);
M328J19-4A (08/31/21);
M328J19-3A (08/31/21);
M328J19-11 (08/31/21);
M328K19-4A (09/30/21);
M328J19-2A (08/31/21)

- NP Thyroid is indicated as replacement or supplemental therapy in patients with hypothyroidism of
 any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis; as
 pituitary TSH suppressants, in the treatment or prevention of various types of euthyroid goiters,
 including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular
 goiter, and in the management of thyroid cancer.
- Per Acella, patients being treated for hypothyroidism who receive subpotent NP Thyroid, 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 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.
- To date, Acella has received 43 reports of serious adverse events that could possibly be related to this recall.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled NP Thyroid tablets.
- Anyone with an existing inventory of the recalled product should stop use and quarantine the product immediately.
- For more information regarding this recall, contact Acella Pharmaceuticals at **1-888-424-4341** or email at **recall@acellapharma.com**.



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