

### Acella Pharmaceuticals – Recall of NP Thyroid® (thyroid)

- On September 17, 2020, [Acella Pharmaceuticals announced](#) a voluntary, consumer-level recall of one lot of 15 mg and one lot of 120 mg [NP Thyroid® \(thyroid\)](#) tablets 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).

Product Description	NDC#	Lot # (Expiration Date)
NP Thyroid 15, thyroid tablets, ¼ grain (15 mg)	42192-327-01	M327E19-1 (October 2020)
NP Thyroid 120, thyroid tablets, 2 grain (120 mg)	42192-328-01	M328F19-3 (November 2020)

- NP Thyroid tablets are indicated as replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis and 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 sub potent 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 four reports of adverse events for the lot numbers possibly related to this recall.
- Patients currently taking NP Thyroid should not discontinue use without contacting their physician or health care provider for further guidance and/or a replacement prescription.
- Patients who have the recalled NP Thyroid should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled NP Thyroid.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.

- Contact Acella by phone at **1-888-280-2044** or by email at **recall@acellapharma.com** for further information regarding this recall.



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