



Voluntary Recall

Out of an abundance of caution, we have decided to voluntarily recall certain lots of 15mg, 30mg, 60mg, 90mg and 120mg of NP Thyroid® that do not meet our stringent quality standards following our routine testing. The products are being recalled because testing has found these lots to be subpotent. This means the product contains less than 90% of the amount of levothyroxine (T4) and/or liothyronine (T3) specified on the label. This is a targeted recall, meaning it only relates to specific lots and samples of the medication. NP Thyroid® continues to remain widely available; NP Thyroid® is not on back order or allocation. We have no reason to believe that any other lots of NP Thyroid® are outside of these standards.

For questions about the recall, please email recall@acellapharma.com or contact our dedicated recall hotline at 1-888-424-4341, Monday through Friday from 8:00 a.m. to 5:00 p.m. 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.



For Important Safety Information, including BOXED WARNING, please see reverse side.

Marketed by Acella Pharmaceuticals, LLC., Alpharetta, GA 30005 ML-0729 0421-01

List of 35 Recalled Commercial Lots (100-count Bottles)

NDC	PRODUCT	Lot #	Exp. Date
42192-327-01	NP Thyroid® 15mg Tablets	M327D20-1	3/31/2022
		M327D20-3	3/31/2022
		M327H19-3A	7/31/2021
		M327L19-1	4/30/2021
42192-329-01	NP Thyroid® 30mg Tablets	M329D20-1	3/31/2022
		M329D20-2	3/31/2022
		M329D20-3	3/31/2022
42192-330-01	NP Thyroid® 60mg Tablets	M330D20-1	3/31/2022
		M330D20-2	3/31/2022
		M330J19-2A	8/31/2021
		M330J19-4A	8/31/2021
		M330J19-5A	8/31/2021
		M330J19-6A	8/31/2021
		M330J19-7A	8/31/2021
		M330J19-9A	8/31/2021
		M330K19-10	9/30/2021
		M330K19-1A	9/30/2021
42192-331-01	NP Thyroid® 90mg Tablets	M331J19-10A	8/31/2021
		M331J19-11	8/31/2021
		M331J19-2A	8/31/2021
		M331J19-6A	8/31/2021
		M331K19-1	9/30/2021
		M331K19-2	9/30/2021
42192-328-01	NP Thyroid® 120mg Tablets	M328H19-2B	8/31/2021
		M328J19-11	8/31/2021
		M328J19-2A	8/31/2021
		M328J19-3A	8/31/2021
		M328J19-4A	8/31/2021
		M328J19-5A	8/31/2021
		M328J19-6A	8/31/2021
		M328J19-7A	8/31/2021
		M328K19-2	9/30/2021
		M328K19-4A	9/30/2021

List of 3 Recalled Sample Lots (7-count Bottles)

NDC	PRODUCT	Lot #	Exp. Date
42192-327-07	NP Thyroid® 15mg Tablets	M327D20-1	3/31/2022
42192-329-07	NP Thyroid® 30mg Tablets	M329D20-2	3/31/2022
42192-328-07	NP Thyroid® 120mg Tablets	M328J19-9B	8/31/2021

IMPORTANT SAFETY INFORMATION

WARNING: Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

IMPORTANT RISK INFORMATION

Thyroid hormones, including NP THYROID[®], should not be used either alone or in combination with other drugs for the treatment of obesity or weight loss. In patients with normal thyroid levels, doses of NP THYROID[®] used daily for hormone replacement are not helpful for weight loss. Larger doses may result in serious or even life-threatening events, especially when used in combination with certain other drugs used to reduce appetite.

WHAT IS NP THYROID[®]?

NP THYROID[®] (thyroid tablets, USP) is a prescription medicine that is used to treat a condition called hypothyroidism from any cause, except for cases of temporary hypothyroidism, which is usually associated with an inflammation of the thyroid (thyroiditis). It is meant to replace or supplement a hormone that is usually made by your thyroid gland. NP THYROID[®] is also used in the treatment and prevention of normal functioning thyroid goiters, such as thyroid nodules, Hashimoto's thyroiditis, multinodular goiter, and in the management of thyroid cancer.

IMPORTANT RISK INFORMATION (cont'd)

- Do not use NP THYROID[®] if you have hyperthyroidism, overactive thyroid, uncorrected adrenal problems, or are allergic to any of its ingredients.
- Tell your doctor about any other medical conditions you may have, especially heart disease, diabetes, blood clotting problems, and adrenal or pituitary gland problems. The dose of other drugs you may be taking to control these conditions may have to be changed while you are taking NP THYROID[®].
- Tell your doctor immediately if you experience chest pain; increased pulse rate; rapid, strong, irregular heartbeat; excessive sweating; or any other unusual event.
- If you have diabetes, check your blood sugar levels and/or the glucose in your urine, as ordered by your doctor and immediately tell your doctor if there are any changes.
- If you are taking oral anticoagulants, blood clotting status should be checked often by your doctor.
- Partial loss of hair may be experienced by children in the first few months of thyroid therapy, but this will usually go away on its own.
- Tell your doctor if you are allergic to any foods or drugs, are pregnant or plan to become pregnant, are breastfeeding or are taking any other drugs, as well as prescription and over-the-counter products.
- Use NP THYROID[®] only as ordered by your doctor. Do not stop or change the amount you take, or how often you take it, unless told to do so by your doctor.