

May 3, 2021

COM-2021-025

RECALL NOTIFICATION



FDA PUBLICATION DATE:

April 30, 2021

**DRUG NAME: NP Thyroid®
(Thyroid Tablets, USP)**

**COMPANY: Acella
Pharmaceuticals, LLC**

REASON: Sub potency

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on April 30, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary drug recall for certain lots of the following product: NP Thyroid®, 15mg, 30mg, 60mg, 90mg, and 120mg, manufactured by Acella Pharmaceuticals, LLC.

The voluntary recall is due to a quality tests results showing that drug lots are sub potent. Product concentration was less than 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4). The patients could experience signs and symptoms related to hypothyroidism (e.g., 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, and early miscarriage, among others).

The company has 43 reports of serious adverse events that could be related to this recall.

Affected lots:

Product	NDC	Lot #	Expiration Date	Distribution Dates
NP Thyroid® 15mg Tablets	42192-327-01	M327D20-1	3/31/2022	08/11/2020 - 10/06/2020
NP Thyroid® 15mg Tablets	42192-327-01	M327D20-3	3/31/2022	07/20/2020 - 09/29/2020
NP Thyroid® 15mg Tablets	42192-327-01	M327H19-3A	7/31/2021	06/23/2020 - 07/08/2020
NP Thyroid® 15mg Tablets	42192-327-01	M327L19-1	4/30/2021	03/04/2020 - 04/30/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328H19-2B	8/31/2021	09/16/2020 - 09/24/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-11	8/31/2021	04/15/2020 - 06/09/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-2A	8/31/2021	07/28/2020 - 08/07/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-3A	8/31/2021	08/07/2020 - 09/02/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-4A	8/31/2021	08/31/2020 - 02/09/2021
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-5A	8/31/2021	09/04/2020 - 11/18/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-6A	8/31/2021	09/14/2020 - 10/16/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328J19-7A	8/31/2021	09/29/2020 - 10/14/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328K19-2	9/30/2021	04/02/2020 - 10/02/2020
NP Thyroid® 120mg Tablets	42192-328-01	M328K19-4A	9/30/2021	09/25/2020 - 11/25/2020
NP Thyroid® 30mg Tablets	42192-329-01	M329D20-1	3/31/2022	05/12/2020 - 02/02/2021
NP Thyroid® 30mg Tablets	42192-329-01	M329D20-2	3/31/2022	06/22/2020 - 09/08/2020
NP Thyroid® 30mg Tablets	42192-329-01	M329D20-3	3/31/2022	07/13/2020 - 09/28/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330D20-1	3/31/2022	08/11/2020 - 03/16/2021
NP Thyroid® 60mg Tablets	42192-330-01	M330D20-2	3/31/2022	09/25/2020 - 10/12/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-2A	8/31/2021	06/16/2020 - 06/16/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-4A	8/31/2021	07/28/2020 - 08/19/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-5A	8/31/2021	06/18/2020 - 06/24/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-6A	8/31/2021	07/01/2020 - 07/15/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-7A	8/31/2021	06/10/2020 - 06/30/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330J19-9A	8/31/2021	05/29/2020 - 06/04/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330K19-10	9/30/2021	03/31/2020 - 05/07/2020
NP Thyroid® 60mg Tablets	42192-330-01	M330K19-1A	9/30/2021	08/19/2020 - 08/26/2020

Product	NDC	Lot #	Expiration Date	Distribution Dates
NP Thyroid® 60mg Tablets	42192-330-01	M330K19-9	9/30/2021	05/04/2020 - 08/26/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331J19-10A	8/31/2021	08/19/2020 - 08/27/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331J19-11	8/31/2021	04/03/2020 - 04/27/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331J19-2A	8/31/2021	07/28/2020 - 08/05/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331J19-6A	8/31/2021	09/29/2020 - 10/08/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331K19-1	9/30/2021	04/27/2020 - 06/10/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331K19-2	9/30/2021	04/23/2020 - 07/29/2020
NP Thyroid® 90mg Tablets	42192-331-01	M331K19-6	9/30/2021	06/11/2020 - 07/08/2020
NP Thyroid® 15mg Tablets	42192-327-07	M327D20-1	3/31/2022	08/04/2020 - 03/19/2021
NP Thyroid® 30mg Tablets	42192-329-07	M329D20-2	3/31/2022	08/14/2020 - 03/19/2021
NP Thyroid® 120mg Tablets	42192-328-07	M328J19-9B	8/31/2021	01/25/2021 - 03/19/2021

Pharmacy required action(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- Advise patients to contact their physician if they have experienced any problems related to taking or using this product.

Contact information:

- For questions, contact Acella Pharmaceuticals at recall@acellapharma.com or by phone at 1-888-424-4341, Monday through Friday from 8:00 am – 5:00 pm ET.

Remember you can report adverse events related to this or any other drug product at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) by any of the following ways:

- Complete and submit the [MedWatch Online Voluntary Reporting Form](#) online.

- [Download](#) FDA Form 3500 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.

Additional information can be found at: [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#).

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2021). Acella Pharmaceuticals, LLC, Issues Voluntary Nationwide Recall of Certain Lots of NP Thyroid® (Thyroid Tablets, USP) Due to Sub Potency. Retrieved May 3rd, 2021 from <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-certain-lots-np-thyroidr-thyroid-0>
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>
- MedWatch Online Voluntary Reporting Form. Available at: <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>