



<<Date>>

<<First Name>> <<Last Name>>

<< Address line 1>>

<< Address line 2>>

<<City>> <<ST>> << Zip Code>>

### **IMPORTANT RECALL INFORMATION**

Dear <<First Name>> <<Last Name>>,

We are sending you information about NP Thyroid® 15 mg and 120 mg tablets that may be valuable to you.

On September 18, 2020, Acella Pharmaceuticals, LLC issued a recall of NP Thyroid® 15 mg and 120 mg tablets. **This recall was issued because these tablets may be sub potent, which could be a health hazard or safety risk to plan members using product affected by this recall.** Sub potent means that the product contains less than the required amount of the active ingredient(s).

Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent NP Thyroid®, may experience signs and symptoms of hypothyroidism (underactive thyroid) such as 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 both elderly and patients with underlying cardiac disease toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia.

Our records show you may have received a prescription for the following product recently from your retail pharmacy:

[Drug Name]

A list of the affected products is provided at the end of this letter.

(over)

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark. Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information. This information is not a substitute for medical advice or treatment. Talk to your doctor or health care provider about this information and any health-related questions you have. CVS Caremark assumes no liability whatsoever for the information provided or for any diagnosis or treatment made as a result of this information.

**Acella Pharmaceuticals, LLC advises that patients should talk to their healthcare professional before they stop taking their NP Thyroid medicine. Please call your doctor right away for advice if you may be using affected product or if you do not know if you used affected product.** Your doctor is familiar with your medical history and can suggest the best treatment option for you. If you need a prescription for a different medicine, please contact your doctor.

If you received any recalled product from your retail pharmacy, please contact the pharmacy that filled your prescription for more information including return instructions.

To avoid an interruption in therapy, you should not return the product until after you have received your replacement prescription.

For more information, please call Acella Pharmaceuticals, LLC toll-free at 1-888-280-2044, Monday through Friday, 8:00 am to 5:00 pm (ET). You may also call the FDA toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit [www.fda.gov](http://www.fda.gov).

- This material is available in other languages. Please call our member services department at the toll-free number listed on your benefit ID card. TTY users should call 1-800-863-5488.
- Esta información está disponible en otros idiomas. Por favor llame a nuestro departamento de servicios al cliente al número gratuito que aparece en su tarjeta de identificación. Los usuarios de equipo teleescritor (TTY) deben llamar al 1-800-863-5488.

Sincerely,

CVS Caremark® Medical Affairs

Affected Products and Lot Numbers:

<b>Affected Product</b>	<b>NDC #</b>	<b>Lot #</b>
NP Thyroid® 15 mg tablets	42192-0327-01	M327E19-1 exp. 10/2020
NP Thyroid® 120 mg tablets	42192-0328-01	M328F19-3 exp. 11/2020