



February 5, 2021

Dear Valued Patient,

We're sending you this letter because you are prescribed NATPARA (parathyroid hormone) 75-mcg or NATPARA 100-mcg through the Special Use Program and your OnePath® Patient Support Manager has been unable to reach you by phone.

We are providing you with this letter to inform you of a potential shipping delay. An inventory processing delay, compounded by a severe winter storm during the week of February 1, 2021, has impacted the NATPARA® shipping schedule. There are some patients who could experience a brief supply interruption of NATPARA 75-mcg or NATPARA 100-mcg between now and the end of the second week of February. It is therefore with a sense of urgency that we are contacting you at this time. Pending any additional unanticipated delays, we have already rescheduled shipments and expect the supply interruption to be fully addressed by February 11, 2021.

**ACTION NEEDED: Please contact your OnePath Patient Support Manager at 866-888-0660 at your earliest convenience so we can provide you with urgent information related to your NATPARA shipments and your prescribing physician.**

We are in the process of communicating with all prescribing physicians to notify them about this inventory issue and shipping delay. If a new prescription is needed, based on your physician's medical judgement, please make sure your prescribing physician contacts Takeda OnePath at 866-888-0660 as soon as possible. If your Physician has previously submitted an alternative back-up prescription form, that alternative prescription will be filled to avoid an interruption. Our goal is to supply you with the backup prescription that is on file, if needed. Your regular prescription will resume once that dose is again available. A Takeda OnePath® Patient Support Manager will follow up with you and answer questions related to the processing of this prescription or your scheduled shipments.

This shipping delay is NOT the result of any quality or manufacturing issues. This situation is not impacting NATPARA 50-mcg or NATPARA 25-mcg. However, based on the supply demands of the Special Use Program, we continue to closely monitor all NATPARA doses. We are committed to supply continuity and will provide a general update on all NATPARA doses by the end of March 2021.

As a patient who is receiving NATPARA through the Special Use Program, we want to remind you that each NATPARA cartridge under the Special Use Program (single dose use) is intended for one use only, and that used cartridges with remaining product are to be returned to Takeda in accordance with the Special Use Program (single dose use) instructions. Non-compliance with the rules under the Special Use Program (single dose use) could result in termination of your ability to receive NATPARA product through the program.

It is important to remember that any potential interruption or reduction in the daily dose of NATPARA can cause a decrease in blood calcium levels (severe hypocalcemia) which can be dangerous. We appreciate your patience.

We recognize the important medical need that NATPARA fills for patients like you who are living with chronic hypoparathyroidism. We appreciate your patience.

Cheryl Schwartz

Rick Ascroft



Head of U.S. Rare Disease Business Unit      Senior Vice President, Patient Services & Managed Markets

### **What is NATPARA® (parathyroid hormone) for Injection?**

- NATPARA is a prescription parathyroid hormone used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low parathyroid hormone blood levels (hypoparathyroidism).
- NATPARA is only for people who do not respond well to treatment with calcium and active forms of vitamin D alone, because it may increase the possible risk of bone cancer (osteosarcoma).
- NATPARA was not studied in people with hypoparathyroidism caused by calcium-sensing receptor mutations.
- NATPARA was not studied in people who get sudden hypoparathyroidism after surgery.
- It is not known if NATPARA is safe and effective for children 18 years of age and younger. NATPARA should not be used in children and young adults whose bones are still growing.

### **Important Safety Information**

#### **What is the most important information I should know about NATPARA?**

##### **Warning: Possible bone cancer (osteosarcoma).**

- During animal drug testing, NATPARA caused some rats to develop a bone cancer called osteosarcoma. It is not known if people who take NATPARA will have a higher chance of getting osteosarcoma. Tell your doctor right away if you have pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch.
- **NATPARA is only available through the NATPARA Risk Evaluation and Mitigation Strategy (REMS) Program.** The purpose of the NATPARA REMS program is to inform patients about the potential risk of osteosarcoma associated with the use of NATPARA. For more information about this REMS program, call 1-855-NATPARA (628-7272) or go to [www.NATPARAREMS.com](http://www.NATPARAREMS.com).

#### **NATPARA may cause other serious side effects, including:**

##### **High blood calcium (hypercalcemia)**

- NATPARA can cause some people to have a higher blood calcium level than normal.
1. Your doctor should check your blood calcium before you start and during your treatment with NATPARA.
  2. Tell your doctor if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs that you have too much calcium in your blood.

##### **Low blood calcium (hypocalcemia)**

- People who stop using or miss a dose of NATPARA may have an increased risk of severe low blood calcium levels.
- Tell your doctor if you have tingling of your lips, tongue, fingers and feet, twitching of face muscles, cramping of feet and hands, seizures, depression, or have problems thinking or remembering.



**Who should not use NATPARA?**

- **Do not use NATPARA** if you are allergic to parathyroid hormone or any of the ingredients in NATPARA.

**What should I tell my healthcare provider before using NATPARA?**

- **Before you start using NATPARA, tell your doctor about all of your medical conditions. Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**What are the possible side effects of NATPARA?**

- **NATPARA may cause serious side effects like allergic (hypersensitivity) reaction, including anaphylaxis.** Tell your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - swelling of your face, lips, mouth, or tongue
  - breathing problems
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - fast heartbeat
  - itching
  - rash
  - hives
- **The most common side effects of NATPARA include:** tingling, tickling, or burning feeling of the skin, low or high blood calcium, headache, nausea, reduced sense of touch or sensation, diarrhea, vomiting, pain in joints, too much calcium in urine, and pain in limbs.

**Enclosure:** NATPARA Full Prescribing Information

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