



December 22, 2020

Dear Valued Patient,

We are writing to share a supply-status update to the information we provided during the week of December 14, regarding the potential for near-term supply interruptions of NATPARA® (parathyroid hormone) for Injection that may impact U.S. patients receiving NATPARA through the Special Use Program.

Since that supply update, the manufacturing disruption impacting the availability of NATPARA 100-mcg and NATPARA 75-mcg has now been mitigated. **This means that we are no longer expecting near-term supply interruptions for any NATPARA dose for patients receiving NATPARA through the Special Use Program.** You will continue to receive NATPARA through the Special Use Program according to your current shipping schedule.

Your Takeda OnePath® Patient Support Manager will contact you in the coming days to provide the update that we are no longer expecting near-term supply interruptions for NATPARA and to answer questions related to your next NATPARA shipment or the Special Use Program. If you have any immediate questions or concerns, please contact your Takeda OnePath® Patient Support Manager at 866-888-0660. Patient Support Managers are available Monday through Friday 8:30 AM – 8:00 PM ET.

At this time, we do not anticipate near-term supply interruptions for any NATPARA dose. However, we are closely monitoring all NATPARA doses based on the supply demands of the Special Use Program. We are committed to supply continuity and will provide another update on all NATPARA doses by 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.

Enclosed for your reference is the full NATPARA Prescribing Information and Medication Guide. For additional medical information, please contact your healthcare provider.

We recognize that we have been communicating about supply frequently since October 2020, and we are doing that to ensure that you and your prescriber have time to discuss treatment plans in the event of actual NATPARA supply interruptions. This is especially important because any potential interruption or reduction in the daily dose of NATPARA can cause a sharp



decrease in blood calcium levels (severe hypocalcemia) which can be dangerous. We appreciate your patience during the past few months as we worked to maintain supply continuity.

Wishing you and your family a happy and healthy holiday season,

Cheryl Schwartz  
Head of U.S. Rare Disease Business Unit

Daniel McNamara  
Head of U.S. Patient Services

### 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.

##### 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



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.

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

NATPARA<sup>®</sup> is a registered trademark of Shire-NPS Pharmaceuticals, Inc., a Takeda company.

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