



February 5, 2021

Dear Hypoparathyroidism Association board members and community,

On behalf of Takeda, we are sharing the following NATPARA® (parathyroid hormone) update to inform you of a potential short-term supply interruption for some patients receiving NATPARA 75-mcg or NATPARA 100-mcg through the Special Use Program (SUP).

An inventory processing delay, compounded by a severe winter storm during the week of February 1, 2021, has impacted the NATPARA shipping schedule. As a result, 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. Pending any additional unanticipated delays, we have already rescheduled shipments and expect the supply interruption to be fully addressed by February 11. In the interim, patients may be shipped an alternate prescription should they have one on file.

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

Takeda's OnePath® Patient Support Managers are reaching out to all impacted patients directly to emphasize the urgency of contacting their prescribing physicians to discuss the best treatment approach. **If you are a patient receiving NATPARA 75-mcg or NATPARA 100-mcg, and your OnePath Patient Support Manager hasn't been able to reach you directly about this issue, 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. Please also contact your prescribing physician to discuss the best treatment approach with the goal of avoiding treatment lapses.**

Based on individual prescribers' independent medical judgement, revised treatment plans for patients impacted by this supply interruption may require a new prescription. OnePath will also reach out to prescribers when an alternate prescription is required. If a prescriber activates a back-up prescription, we will ship that patient a 7-day supply of the back-up prescription. After that, a Takeda OnePath Patient Support Manager will follow up with the prescribing physician to confirm that we should resume shipments according to the patient's current prescription.

With patient safety as Takeda's main priority, we are alerting impacted patients and their healthcare providers 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. Specifically, we are emphasizing to impacted patients the importance of working closely with their prescribing physician for important medical recommendations, including frequent monitoring of blood calcium levels and close titration of active vitamin D and calcium supplements if the patient's NATPARA is stopped or the dose is altered (e.g., as a result of supply interruption) to avoid hypocalcemia.

We recognize the important medical need that NATPARA fills for the hypoparathyroidism community. We regret this supply interruption and are working with urgency to maintain supply continuity for SUP patients.



Cheryl Schwartz
Head of US Rare Disease Business Unit



Tom Koutsavlis
Head of US Medical Affairs

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.

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.
 - Your doctor should check your blood calcium before you start and during your treatment with NATPARA.
 - 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.

Tell your doctor right away if you have any of these signs and symptoms of **high or low blood calcium** levels.

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.

These are not all the possible side effects of NATPARA. For more information, talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call **1-800-FDA-1088**.

Please go to https://www.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf for the Full Prescribing Information and Medication Guide.

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