



September 10, 2024

Dear Valued Patient,

As follow up to our October 2022 communication (enclosed), the purpose of this letter is to remind you that Takeda will discontinue global manufacturing of NATPARA® (parathyroid hormone) for Injection at the end of December 2024. We understand that you likely have questions as the manufacturing end date approaches and are here to support you through this transition.

Our priority remains to maintain treatment continuity for patients currently receiving NATPARA under the U.S. NATPARA Special Use Program through our previously communicated manufacturing discontinuation at the end of December 2024. Beyond 2024, we intend to supply available doses until inventory is depleted or expired. We continue to closely monitor supply across all NATPARA doses and will provide additional updates to you and your physician ahead of any potential supply interruption or depletion.

Transitioning To Alternate Treatment

We encourage you to contact your healthcare team ahead of the manufacturing discontinuation date to discuss longer-term treatment plans. Starting the conversation with your healthcare team now will allow sufficient time for you to develop an appropriate individual treatment plan.

If you stop taking NATPARA or transition to an alternate therapy after consulting with your healthcare team, please ensure you and your prescribing healthcare provider notify Takeda. To support this process, we sent a NATPARA Special Use Program Transition Acknowledgement Form to your healthcare provider. Per the U.S. NATPARA Special Use Program requirements, please remember to return all used and unused NATPARA cartridges to Takeda.

Should there be a clinically significant need for you to return to the U.S. NATPARA Special Use Program, your healthcare provider may resubmit for consideration. A full resubmission, including a completed Case Report Form with substantial clinical justification, will be required. Re-enrollment in the U.S. NATPARA Special Use Program is dependent on NATPARA supply availability.

Takeda Support

We remain steadfastly committed to supporting you throughout this transition. Our NATPARA Special Use Program support team is here to help you. If you have any questions, please contact your NATPARA Special Use Program manager at 1-866-888-0660, Monday through Friday 8:30 AM – 8:00 PM ET.

Sincerely,

Jennifer Norton
Senior Vice President, U.S. Patient and Market Access
Takeda Pharmaceuticals U.S.A., Inc.



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.

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 <http://www.FDA.gov/medwatch>.

Please go to https://www.shirecontent.com/PI/PDFs/NATPARA_USA_ENG.pdf for the full Prescribing and Medication Guide. For additional medical information, please contact your healthcare provider.

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