



September 6, 2019

US Recall of NATPARA® (parathyroid hormone) for Injection

IMPORTANT INFORMATION REQUIRING ACTION

Dear Valued Patient,

The purpose of this letter is to inform you that Takeda has issued a US recall for all doses of NATPARA® (parathyroid hormone) for Injection (25 mcg, 50 mcg, 75 mcg, and 100 mcg). The recall is effective immediately. The safety profile of NATPARA remains consistent with the product label. As of the date of this recall, Takeda is not aware of any adverse events directly related to this matter. After discussions with the US FDA, the company is issuing this recall as a precaution.

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

This recall is due to a potential issue related to rubber particulates originating from the rubber septum of the NATPARA cartridge. During the 14-day NATPARA treatment period, the septum is punctured by a needle each day to obtain the daily dosage of medicine solution. When the septum is repeatedly punctured, it is possible that small rubber fragments may detach into the cartridge.

It is critically important that you contact your prescribing healthcare provider, who has also received this important information. As part of this communication, and consistent with the product label, we are alerting NATPARA patients and prescribers that stopping NATPARA abruptly can cause a sharp decrease in blood calcium levels (severe hypocalcemia) which can have serious health consequences. You need to be under close supervision by your healthcare provider to discuss your individual treatment plan, including frequent monitoring of your blood calcium levels and close titration of active vitamin D and calcium supplements upon stopping NATPARA to avoid low blood calcium (hypocalcemia).

In addition, a OnePath® Patient Support Manager will be contacting you to answer any questions you may have about the content of this letter.

Takeda is committed to supply integrity, and we are working closely with the FDA to resolve the issue and resume supply as soon as possible.

We sincerely regret the impact this interruption has on you.

To contact a OnePath Patient Support Manager, please call 1-866-888-0660. OnePath is available Monday through Friday, 8:30am to 8:00pm, Eastern Time.

Sincerely,



Daniel McNamara
Head of US Patient Services
Takeda Pharmaceutical Company Limited

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.
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.

Please see [Full Prescribing Information](#), including Boxed Warning for potential risk of osteosarcoma.

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

OnePath® is a registered trademark of Shire Human Genetic Therapies, Inc., a Takeda company.

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