



## Message About the US NATPARA Recall

**Cambridge, MA, September 13, 2019** --- On September 5, 2019, Takeda issued a US recall for all doses of NATPARA<sup>®</sup> (parathyroid hormone) for Injection (25 mcg, 50 mcg, 75 mcg, and 100 mcg). The recall is being conducted after discussions with the FDA, which has classified it as a Pharmacy Level recall due to the potential for rubber particulate from the rubber septum component part of the NATPARA cartridge to enter into the drug solution. Patients do not need to return or discard the NATPARA they have on-hand. But, it is imperative that patients immediately see their healthcare provider before stopping NATPARA. Doing so will help patients discontinue the medicine as safely as possible, in a supervised setting, including frequent monitoring of blood calcium levels and close titration of active vitamin D and calcium supplements upon stopping NATPARA to avoid low blood calcium. You can read more information about the NATPARA recall [here](#).

We recognize that the recall has been extremely difficult for our NATPARA patients and their families. Since the recall began on September 5, 2019, our dedicated OnePath team has reached out to the more than 2,000 NATPARA patients in the US with information and support. Our commitment to patients remains our highest priority. We are working urgently with the FDA on a number of potential solutions to bring this critical medicine back to patients as quickly as possible and will continue to keep patients and healthcare providers informed.

If you are a patient with questions, please reach out to our OnePath patient services team at 866-888-0660. Healthcare providers with questions should call 800-828-2088.

We are committed to resolving this critical issue quickly and sincerely regret the impact this recall is having on patients and their families, as well as the broader hypoparathyroidism community.

### What is NATPARA<sup>®</sup> (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.
  - 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> or call **1-800-FDA-1088**.

**Please see [Full Prescribing Information](#), [Medication Guide](#), and [Instructions for Use](#) for NATPARA.**

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