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® (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.

About NATPARA® (parathyroid hormone) for Injection in the US

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

Limitations of Use:

- Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.
- NATPARA was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
- NATPARA was not studied in patients with acute post-surgical hypoparathyroidism.

IMPORTANT SAFETY INFORMATION

WARNING: POTENTIAL RISK OF OSTEOSARCOMA

In male and female rats, parathyroid hormone caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. A risk to humans could not be excluded.

Because of the potential risk of osteosarcoma, prescribe NATPARA only to patients who cannot be well-controlled on calcium and active forms of vitamin D and for whom the potential benefits are considered to outweigh the potential risk.

Avoid use of NATPARA in patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma or patients with a history of prior external beam or implant radiation therapy involving the skeleton).

NATPARA is available only through a restricted program called the NATPARA REMS Program.

For more information about the NATPARA REMS program, call 1-855-NATPARA or go to www.NATPARAREMS.com.

Contraindications:

NATPARA is contraindicated in patients with a known hypersensitivity to any component of NATPARA. Hypersensitivity reactions (e.g., anaphylaxis, angioedema, and urticaria) have occurred with NATPARA.

Warnings and Precautions:

Hypercalcemia*:* Severe hypercalcemia has been reported with NATPARA. The risk is highest when starting or increasing the dose of NATPARA but can occur at any time. Monitor serum calcium and patients for signs and symptoms of hypercalcemia. Treat hypercalcemia per standard practice and consider holding and/or lowering the dose of NATPARA if severe hypercalcemia occurs.

Hypocalcemia: Severe hypocalcemia has been reported in patients taking NATPARA, including cases that resulted in seizures. The risk is highest with interruption or discontinuation of NATPARA treatment but can occur at any time. Monitor serum calcium and patients for signs and symptoms of hypocalcemia, and replace calcium and vitamin D if indicated in patients interrupting or discontinuing NATPARA to prevent severe hypocalcemia.

Digoxin Toxicity: Hypercalcemia increases the risk of digoxin toxicity. In patients using NATPARA concomitantly with digoxin, monitor serum calcium more frequently and increase monitoring when initiating or adjusting NATPARA dose.

Hypersensitivity: There have been reports of hypersensitivity reactions in patients taking NATPARA. Reactions included anaphylaxis, dyspnea, angioedema, urticaria, and rash. If signs or symptoms of a serious hypersensitivity reaction occur, discontinue treatment with NATPARA, treat hypersensitivity reaction according to the standard of care, and monitor until signs and symptoms resolve. Monitor for hypocalcemia if NATPARA is discontinued.

Adverse Reactions:

The most common adverse reactions associated with NATPARA and occurring in greater than 10% of individuals were: paresthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoaesthesia, diarrhea, vomiting, arthralgia, hypercalciuria and pain in extremity.

Drug Interactions:

Alendronate: Co-administration of alendronate and NATPARA leads to reduction in the calcium sparing effect, which can interfere with the normalization of serum calcium. Concomitant use of NATPARA with alendronate is not recommended.

Use in Specific Populations:

There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The safety and efficacy in pediatric patients have not been established

Please see Full Prescribing Information, including Boxed Warning for potential risk of osteosarcoma.

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