Drug recall notice for Natpara

We want to alert you to the recall of all doses of Natpara (parathyroid hormone) on Sept. 6, 2019.[1] We recommend you review your medical records and contact all patients for whom you have prescribed Natpara to warn them of the recall to ensure safe discontinuation of the medication. We would like to remind you that abrupt discontinuation of Natpara or dose interruption in patients can result in severe hypocalcemia as stipulated in the Natpara Full Prescribing Information.[2]

Due to removal of this drug from the market, we have listed an alternative option below. It is important to note that according to the prescribing information and the American Association of Clinical Endocrinologists, Natpara use is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Therefore, your patient(s) may have already tried or are currently taking this alternative.[3]

Takeda voluntarily recalled all doses of Natpara (25 mcg, 50 mcg, 75 mcg, 100 mcg). This recall was initiated 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.[1]

This drug is used for the treatment of hypocalcemia in patients with hypoparathyroidism as an adjunct to calcium and vitamin D supplementation.[2]

Drug product and NDCs included in this recall:

NDC	Product description/strength
68875-0202-02	Natpara injection 25 mcg
68875-0203-02	Natpara injection 50 mcg
68875-0204-02	Natpara injection 75 mcg
68875-0205-02	Natpara injection 100 mcg

Information for patients[1]:

- 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 U.S. Food and Drug Administration (FDA), the company is issuing this recall as a precaution.

- As part of this communication, and consistent with the product label, Takeda is 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.
- For any general questions regarding the recall of this product, please contact a Takeda OnePath patient support manager at:
    - 1-866-888-0660 (live calls received Monday through Friday, 8:30 a.m. to 8 p.m., Eastern time)
- Consumers should also contact their physicians or healthcare providers if they have experienced any problems that may be related to taking or using this drug product.
- To determine if a specific product has been recalled, patients should look at the drug name and company name on the label of their prescription bottles. If the information is not on the bottle, patients should contact the pharmacy that dispensed the medicine.
- Patients should contact their pharmacists or physicians to discuss their treatment options if their medicine is included in this recall.
- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

    - **Online:** Complete and submit the report at **www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home**
      • Select "Consumer/Patient (FDA Form 3500B)."

    o **Regular mail or fax:** Download form at **www.fda.gov/node/360547** .
      • Select "Form FDA 3500B – Voluntary Reporting for Consumers" and submit by mail to the address on the form or by fax to **1-800-FDA-0178**.

Recommendation:

Preferred formulary alternative:

Recalled medication	Preferred alternative
Natpara injection	calcitriol

- To access CarePlus' formulary drug list, go to: **www.careplushealthplans.com/medicare-plans/2020-prescription-drug-guides**

References:

1. "Takeda Issues US Recall of NATPARA® (parathyroid hormone) for Injection Due to the Potential for Rubber Particulate." Sept. 5, 2019. www.takeda.com/en-us/newsroom/news-releases/2019/takeda-issues-us-recall-of-natpara-parathyroid-hormone-for-injection-due-to-the-potential-for-rubber-particulate/
2. Natpara Full Prescribing Information. Revised December 2018. www.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf
3. Postoperative Hypoparathyroidism, *Endocrine Practice* 2015; 21(No. 6), 675.