## Takeda – Recall of Natpara® (parathyroid hormone)

- On September 5, 2019, Takeda announced a voluntary patient-level recall of all doses of Natpara (parathyroid hormone) injection 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 Natpara solution. When the septum is repeatedly punctured, it is possible that small rubber fragments may detach into the cartridge.

| Product Description | Strength | NDC# |
|---|---|---|
| Natpara (parathyroid hormone) injection | 25 mcg | 68875-0202-02 |
| | 50 mcg | 68875-0203-02 |
| | 75 mcg | 68875-0204-02 |
| | 100 mcg | 68875-0205-02 |

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

- Takeda is communicating directly with healthcare professionals, patients, and specialty pharmacies in the U.S. regarding the actions required as a result of the recall.

- Consistent with the product labeling, Takeda is alerting Natpara patients and prescribers that discontinuing Natpara abruptly can cause a sharp decrease in blood calcium levels (severe hypocalcemia) which can result in serious health consequences.

- It is critically important that patients contact their prescribing healthcare provider to discuss their individual treatment plan and ensure close supervision, 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 (hypocalcemia).

- Takeda is working closely with the FDA to resolve the issue and resume supply as soon as possible.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Natpara injection.

- Healthcare providers with medical-related questions or other questions about the Natpara recall should contact Takeda Medical Information at **1-800-828-2088** (option 2). Patients in the U.S. with questions about the Natpara recall should contact OnePath at **1-866-888-0660**.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.