DOCTORS HEALTHCARE PLANS, INC.

Drug recall notice for: <u>All Lots</u> of NATPARA (Parathyroid Hormone) for Injection

Takeda Pharmaceutical Company Limited ("Takeda") announced that the company is issuing a US recall for all doses of NATPARA® (parathyroid hormone) for Injection (25 mcg, 50 mcg, 75 mcg, and 100 mcg). This recall is being conducted after discussions with the FDA and is effective immediately 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.

<u>What your patients should know:</u>

Please refer your patient to the FDA for the most current updates to this drug or have your patient ask their pharmacy for assistance. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/takeda-issues-us-recall-natparar-parathyroid-hormone-injection-due-potential-rubber-particulate

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: www.fda.gov/medwatch/report.htm
- **Regular mail or fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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Voluntary Recall Letter:

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With patient safety as the company's main priority, Takeda is communicating directly with healthcare professionals, patients, and specialty pharmacies in the US 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).

The safety profile of NATPARA remains consistent with the product label. Takeda is working closely with regulatory agencies in relevant markets outside of the US where NATPAR/A is available. NATPAR/A continues to be available in these markets.

NATPARA, a recombinant human protein with the full length 84–amino–acid sequence of endogenous parathyroid hormone (PTH), is currently approved in the US as the only adjunctive treatment for adult patients

with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone (calcium and vitamin D).

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. The financial impact of the recall is currently being assessed in conjunction with the remediation plan.

Healthcare providers with medical-related questions or other questions about the NATPARA recall should contact Takeda Medical Information at +1-800-828-2088 and select Option 2. Patients in the US with questions about the NATPARA recall should contact OnePath at +1-866-888-0660. For full prescribing information, including warnings and precautions,; please visit https://www.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf.External Link Disclaimer

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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.