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ASIA EDITION

Takeda issues US recall of NATPARA, a parathyroid hormone

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Patients are advised to immediately consult their healthcare providers to help ensure safe discontinuation of NATPARA treatment due to potential for rubber particulate

Takeda Pharmaceutical Company Limited, on 6 Sep 2019, 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.

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. Takeda will share the financial impact once determined.