



September 24, 2019

Subject: IMPORTANT INFORMATION REGARDING NEW PROGRAM FOR OBTAINING AND USING NATPARA® (parathyroid hormone) for injection

Dear Healthcare Provider,

The purpose of this letter is to inform you of a temporary Special Use Program to obtain and use NATPARA (parathyroid hormone) for Injection as a result of the recent recall of NATPARA causing a shortage of available product.

In order to allow continued access of Natpara, Takeda has worked with the FDA to develop a Special Use Program with the intent of allowing NATPARA to be accessed by those patients that are facing severe health consequences due to an inability to receive Natpara.

As part of this program, in order to minimize the potential risk of adverse events, Takeda will supply Natpara multiple-dose cartridge; however, patients must be counseled to use this cartridge for a SINGLE DOSE ONLY, puncturing each cartridge only one time. SEE DOSING and ADMINISTRATION section below for more information.

Obtaining Product: This Special Use Program allows physicians to submit a request to Takeda to explain the severe and/or life threatening medical situation facing the patient, and an adjudication committee will review the case, using criteria reviewed and approved by internal and external medical personnel and the FDA. The Special Use Program is intended to be a temporary program to aid in supply of Natpara to individual patients who are likely to face severe and/or life-threatening health consequences from interruption or discontinuation of Natpara. The program does not and cannot guarantee access to drug to any individual or group of patients. HCPs who believe they have a patient meeting the criteria outlined below should contact Takeda at NatparaSpecialUseProgram@Takeda.com

Once approved through the Takeda adjudication process, which includes an external board certified endocrinologist, and upon order of the physician, product will be provided free of charge and shipped to the physician or, at the physician's direction, to the patient based upon individual circumstances. Product dosage will be aligned as prescribed by the physician and enough NATPARA kits will be provided to allow for a SINGLE USE per cartridge. Takeda will provide a 28-day supply (14 kits containing 28 cartridges). A subsequent 28-day supply will be authorized at approximately day 21, pending confirmation of appropriate accounting of used cartridges returned by the patient, reaffirmation of continued patient need by prescriber and review by the adjudication committee.

These unique administration instructions for use, including retention and collection of cartridge after one single dose (outlined below), must be reviewed in detail with the patient by the prescribing physician prior to the patient receiving product. In order to participate in this program, patients must agree to adhere to the below Dosing/Administration and Product Discard Instructions.

Dosing and Administration: Each NATPARA cartridge under the Special Use Program is intended for SINGLE USE ONLY; the used cartridge with remaining product is to be returned to Takeda as outlined below. Reconstitution and administration should follow the approved package labeling



instructions except that each cartridge should only be used for a SINGLE DOSE. The Patient Consent Form will further detail this requirement directly to the patient and additional training will be offered for dosing and administration, as well as cartridge return, as requested by the Patient or HCP.

Product Discard Instructions: After reconstitution and administration of a single dose per NATPARA cartridge, the HCP must inform the patient that any remaining product should be returned to Takeda, on a regular basis, utilizing the return instructions and shipping materials provided to the patient with each product delivery. Takeda will remind the patient of this requirement periodically and additional training will be offered as deemed necessary. Takeda will perform an accounting of retrieved product and report any deviation back to the Adjudication Committee.

Product Risk: Lots of Natpara were recently recalled causing a shortage of available product. The recall was conducted due to the potential for rubber particulate from the rubber septum component of the NATPARA cartridge to enter the drug solution and clog the needle leading to underdosing. In such cases, there would be a risk of acute hypocalcemia when the patient/healthcare provider is unaware of receiving lower than required doses of Natpara. In its most severe presentation, hypocalcemia may result in seizures, cardiac arrhythmias, altered mental status and cardiac arrest. There have been no post-marketing reports of clogged needles, sub-dosing or complication reports. During the approved 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. Using each NATPARA cartridge for only a single dose is anticipated to eliminate this from occurring.

Reporting Adverse Events

Adverse reactions or quality problems experienced with the use of this product may be reported to the US FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form <https://www.fda.gov/safety/medical-product-safety-information/forms-reporting-fda> 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 (1-800-332-0178)

Alternatively, adverse events can also be reported to Takeda by calling 1-800-828-2088

Medical Information

You may also contact our medical information department at 1-800-828-2088 if you have any questions about the information contained in this letter or the safe and effective use of NATPARA.

This letter is not intended as a complete description of the benefits and risks related to the use of NATPARA. Please refer to the enclosed full Prescribing Information and Medication Guide. For additional information, please call Takeda at 1-800-828-2088 or visit www.natpara.com.

Sincerely,

Tom Koutsavlis, MD, FRCPC
Head, US Medical

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Enclosure: NATPARA Full Prescribing Information

