

**NATPARA<sup>®</sup>** (parathyroid hormone) for injection

**Risk Evaluation and Mitigation Strategy (REMS)  
Program**

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PRESCRIBER TRAINING MODULE



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# Introduction

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# Introduction



- NATPARA is available only through a restricted program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
  - Prescribers must become certified in the NATPARA REMS Program to be able to prescribe NATPARA
  - Pharmacies must be certified to dispense NATPARA
  - NATPARA must be dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

**NATPARA<sup>®</sup>**

**(parathyroid hormone) for injection**



# Indication



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

- NATPARA is not a parathyroid hormone replacement
  - Limitations of Use:
    - Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
    - NATPARA was not studied in patients with hypoparathyroidism caused by calcium sensing receptor mutations
    - NATPARA was not studied in patients with acute post-surgical hypoparathyroidism

# Boxed Warning



## **WARNING: POTENTIAL RISK OF OSTEOSARCOMA**

- NATPARA causes an increase in the incidence of osteosarcoma in rats
- The increase in rats is dependent on NATPARA dose and treatment duration

*Report suspected adverse reactions to Takeda at 1-855-NATPARA (1-855-628-7272) or to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)*

# Appropriate Patient Selection



- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
  - Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase
  - Pediatric and young adult patients with open epiphyses
  - Patients with hereditary disorders predisposed to osteosarcoma
  - Patients with a prior history of external beam or implant radiation therapy involving the skeleton



# NATPARA REMS Program Information

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# NATPARA REMS Program Information



## Program Overview

- Prescriber Certification
  - Certification consists of training, including successful completion of the Knowledge Assessment and enrolling in the NATPARA REMS Program
- Patient counseling on benefits and risks of NATPARA
- Completion of one-time NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* – required before NATPARA can be dispensed from pharmacy
- Only certified pharmacies can dispense NATPARA

# NATPARA REMS Program



To become certified in the NATPARA REMS program, prescribers must complete the following steps:

1. Review the following:
  - NATPARA Prescribing Information
  - NATPARA *REMS Program: An Introduction*
  - NATPARA *REMS Program Training Module for Prescribers*
2. Successfully complete and submit the Knowledge Assessment at the end of this training module
3. Complete, sign, and submit the one-time NATPARA *REMS Program Prescriber Enrollment Form*

# Prescriber Certification and Enrollment Process



Prescriber certification and enrollment can be completed either online or through a paper-based process:

## 1) Online

- Visit [www.NATPARAREMS.com](http://www.NATPARAREMS.com) and click on the “Prescriber Certification” tab for online certification and enrollment instructions

## 2) Paper-based

- Review the NATPARA Prescribing Information, *NATPARA REMS Program: An Introduction*, and the *NATPARA REMS Program Training Module for Prescribers*
- Complete and submit both the Knowledge Assessment section from the *NATPARA REMS Program Training Module for Prescribers* and the *NATPARA REMS Program Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center via:
  - Fax at 1-844-NAT-REMS (628-7367) or
  - Scan and email to [NATPARAREMS@takeda.com](mailto:NATPARAREMS@takeda.com)

REMS materials may be downloaded from the REMS website at [www.NATPARAREMS.com](http://www.NATPARAREMS.com); alternatively you may request hard copies by calling 1-855-NATPARA (628-7272)

# Patient Counseling on Benefit/Risk Profile



- Prescriber must counsel patients on the benefit/risk profile of NATPARA
  - The NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients
  - Provide patients with copies of the NATPARA *REMS Program Patient Brochure* and the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form*

# Prescription Process



- Complete and sign the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* with each patient prior to initiation of therapy
- Provide patients with a copy of the signed form and a copy of the *NATPARA REMS Program Patient Brochure*
- Submit the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* and prescription for NATPARA to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to [NATPARAREMS@takeda.com](mailto:NATPARAREMS@takeda.com)
- The NATPARA REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and a *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* is on record
- Certified pharmacies will not dispense NATPARA if a prescriber is not certified and/or the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* is not on record
- The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled

# Questions about the NATPARA REMS Program

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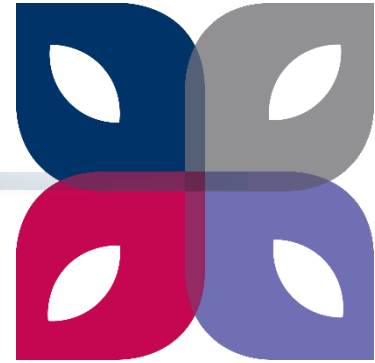


- Visit [www.NATPARAREMS.com](http://www.NATPARAREMS.com)
- Call 1-855-NATPARA (628-7272)



# Knowledge Assessment

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# Knowledge Assessment - Instructions



- You can complete the certification and enrollment process directly online at [www.NATPARAREMS.com](http://www.NATPARAREMS.com) or through a paper-based process as follows:
  - Print out both pages of the Knowledge Assessment questions and the *NATPARA REMS Program Prescriber Enrollment Form*
  - Answer all questions in the Knowledge Assessment (100% passing score required)
  - Complete and sign the *NATPARA REMS Program Prescriber Enrollment Form*
  - Submit the completed Knowledge Assessment and *NATPARA REMS Program Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center via:
    - Fax at 1-844-NAT-REMS (628-7367) or
    - Scan and email to [NATPARAREMS@takeda.com](mailto:NATPARAREMS@takeda.com)
- You will receive correspondence from the NATPARA REMS Program Coordinating Center on your certification status immediately (online) or within 2 business days (paper-based)

# Knowledge Assessment



Complete all 7 questions. Mark only one answer for each question.  
You can also complete the certification and enrollment process online at [www.NATPARAREMS.com](http://www.NATPARAREMS.com)

## Question 1

NATPARA is only available through the NATPARA REMS Program.

- True
- False

## Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

## Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats.

- True
- False

## Question 4

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:

- Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase
- Pediatric and young adult patients with open epiphyses
- Patients with hereditary disorders predisposed to osteosarcoma
- Patients with a prior history or external beam or implant radiation therapy involving the skeleton
- All of the above

# Knowledge Assessment



## Question 5

How often should the *Patient-Prescriber Acknowledgment Form* be completed?

- With each new prescription
- With every refill
- Once a year
- One-time for each new patient

## Question 6

Patients who are controlled on a regimen of calcium and vitamin D should be switched to NATPARA.

- True
- False

## Question 7

Prescribers must counsel patients on the risk/benefit profile for NATPARA.

- True
- False

If faxing your Knowledge Assessment, include your name below:

Prescriber Name: (please print)

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You must complete and submit both the Knowledge Assessment and the NATPARA *REMS Program Prescriber Enrollment Form* to become certified in the NATPARA REMS Program. You can complete the certification and enrollment process online at [www.NATPARAREMS.com](http://www.NATPARAREMS.com) or submit both documents via:

- Fax at 1-844-NAT-REMS (628-7367) or
- Scan and email to NATPARAREMS@takeda.com

# Completion of Training Module



Thank you for completing the NATPARA REMS Program Training Module.

As a reminder, you may complete the certification and enrollment process online at [www.NATPARAREMS.com](http://www.NATPARAREMS.com) or through a paper-based process by completing and submitting the Knowledge Assessment and NATPARA *REMS Program Prescriber Enrollment Form* via:

- Fax: 1-844-NAT-REMS (628-7367) or
- Email: [NATPARAREMS@takeda.com](mailto:NATPARAREMS@takeda.com)

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