

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

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

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TRAINING MODULE FOR PHARMACY  
REPRESENTATIVES



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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
  - Pharmacies must designate an authorized Pharmacy Representative to complete the certification in the NATPARA REMS Program in order to dispense NATPARA
  - Prescribers must be certified in the NATPARA REMS Program in order to prescribe 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

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# Indication



NATPARA is 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 Shire 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
- 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
  - NATPARA can be prescribed only by certified prescribers
  - Prescribers will:
    - Counsel patients about the benefit/risk profile of NATPARA
    - Complete the one-time NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* for each patient
- **Only certified pharmacies may dispense NATPARA**
  - Verification of prescriber certification before dispensing NATPARA
  - Verification of NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* on record for the patient before dispensing NATPARA

# NATPARA REMS Program



- Pharmacies must designate an **authorized pharmacy representative** who will complete the certification process on behalf of the pharmacy

# NATPARA REMS Program



**For your pharmacy to become certified, authorized pharmacy representatives must complete the following steps:**

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

# Enroll in the NATPARA REMS Program



To enroll in the NATPARA REMS Program:

1. Answer the questions in the Knowledge Assessment section of the NATPARA REMS Program Training Module for Pharmacy Representatives
2. Find the NATPARA REMS Program Pharmacy Enrollment Form at [www.NATPARAREMS.com](http://www.NATPARAREMS.com) or request a copy by calling 1-855-NATPARA (628-7272)
  - Complete and sign the enrollment form
3. Submit enrollment form and the Knowledge Assessment section to the NATPARA REMS Program Coordinating Center by:
  - Fax to 1-844-NAT-REMS (628-7367) or
  - Scan and email to [NATPARAREMS@shire.com](mailto:NATPARAREMS@shire.com)

# Pharmacy Representative Responsibilities



- Ensure all relevant staff involved in dispensing of NATPARA are trained on the NATPARA REMS Program requirements as described in the NATPARA *REMS Program Training Module for Pharmacy Representatives*
- Put processes and procedures in place to ensure the following verifications and safe-use conditions are met prior to dispensing NATPARA:
  - Receive the prescription from the NATPARA REMS Program Coordinating Center
  - Verify that the prescriber is certified in the NATPARA REMS program
  - Verify that a NATPARA *REMS Program Patient-Prescriber Acknowledgement Form* is on record for each patient
  - Contact the patient to arrange the date to ship NATPARA once the prescription is filled

# Pharmacy Representative Responsibilities



- Make available to Shire — and/or a designated third party of the FDA — documentation to verify your understanding of and adherence to the requirements of the NATPARA REMS Program
- Recertify in the NATPARA REMS Program if the pharmacy designates someone else as the authorized representative.

# Questions about the NATPARA REMS Program

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# Questions about the NATPARA REMS Program



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

# Knowledge Assessment

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# Knowledge Assessment - Instructions



- To complete the certification process you will need to answer all questions in Knowledge Assessment correctly.
- Print out both pages of Knowledge Assessment questions.
- Fax your Knowledge Assessment and Enrollment Form to: **1-844-NAT-REMS (628-7367)**

**Or**

- Scan and email your Knowledge Assessment and Enrollment Form to: **NATPARAREMS@shire.com**
- You will receive correspondence from the NATPARA REMS Program on your certification status within 2 business days.

# Knowledge Assessment



Complete all 5 questions.

## 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 (check all that apply)

**Prior to distributing each NATPARA prescription, pharmacies need to:**

- Verify that the prescriber is certified in the NATPARA REMS Program
- Verify that a NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* is on record for the patient
- Call the patient to verify that counseling took place with prescriber
- All of the above

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If faxing your Knowledge Assessment, include your name below:

Pharmacy Representative Name: (please print)

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You must complete and submit both the Knowledge Assessment and Enrollment form for your pharmacy to become certified in the NATPARA REMS Program.

Fax to: 1-844-NAT-REMS (628-7367)

Or scan and email to: [NATPARAREMS@shire.com](mailto:NATPARAREMS@shire.com)

# Completion of Training Module



Thank you for completing the NATPARA *REMS Program Training Module*.

To complete your enrollment in the NATPARA REMS Program:

- Find the NATPARA *REMS Program Pharmacy Enrollment Form* at [www.NATPARAREMS.com](http://www.NATPARAREMS.com) or request a copy by calling 1-855-NATPARA (628-7272)
- Complete and sign the enrollment form
- Submit Knowledge Assessment and enrollment form:
  - Fax to 1-844-NAT-REMS (628-7367) or
  - Scan and email to [NATPARAREMS@shire.com](mailto:NATPARAREMS@shire.com)