NATPARA® (parathyroid hormone) for injection

Risk Evaluation and Mitigation Strategy (REMS) Program

TRAINING MODULE FOR PHARMACY REPRESENTATIVES

Reference ID: 3992588

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Natpara®
(parathyroid hormone)
for Injection
25 • 50 • 75 • 100 mcg per dose strength

Introduction

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

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(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

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

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 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

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

Questions about the NATPARA REMS Program

- Visit www.NATPARAREMS.com
- Call 1-855-NATPARA (628-7272)

Knowledge Assessment

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 form the NATPARA REMS Program on your certification status within 2 business days.

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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

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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

If faxing your Knowledge Assessment, include your name below:

Pharmacy Representative Name: (please print)

_____

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

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Or scan and email to: NATPARAREMS@shire.com

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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 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

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