

NATPARA[®] (parathyroid hormone) for injection

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

PRESCRIBER TRAINING MODULE



Contents



Introduction

NATPARA[®] (parathyroid hormone) for injection

- Indication
- **Boxed Warning:** Potential Risk of Osteosarcoma
- Appropriate Patient Selection

NATPARA REMS Program Information

Questions about the NATPARA REMS Program

Knowledge Assessment

Introduction



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[®]

(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 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 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



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 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@shire.com

REMS materials may be downloaded from the REMS website at 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@shire.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



Questions about the NATPARA REMS Program



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

Knowledge Assessment



Knowledge Assessment - Instructions



- You can complete the certification and enrollment process directly online at 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@shire.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

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)

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 or submit both documents via:

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

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