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

Reference ID: 3691249
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
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
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

Reference ID: 3691249
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 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 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 Prescriber 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 Training Module for Prescribers

2. Find the NATPARA REMS Program Prescriber Enrollment Form at [www.NATPARAREEMS.com](http://www.NATPARAREEMS.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
   - Email to NATPARAREEMS@NPSP.COM
Patient Counseling on Benefit/Risk Profile

- Prescriber must counsel patients on the benefit/risk profile of NATPARA
  - The NATPARA REMS 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 Patient Brochure and the NATPARA REMS Patient-Prescriber Acknowledgment Form
Prescription Process

• Complete the NATPARA REMS Patient-Prescriber Acknowledgment Form with each patient prior to initiation of therapy

• Submit NATPARA REMS Patient-Prescriber Acknowledgment Form and prescription for NATPARA to NATPARA REMS Program Coordinating Center by fax or email

• Prescription refills should be sent to NATPARA REMS Program Coordinating Center by fax or email

• The REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and a Patient-Prescriber Acknowledgment Form is on record

• Certified pharmacies will not dispense NATPARA if a prescriber is not certified and/or the 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

• 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

• Email your Knowledge Assessment and Enrollment Form to: NATPARAREMS@NPSP.COM

• You will receive correspondence from the NATPARA REMS Program on your certification status within 2 business days.
Complete all 7 questions. Mark only one answer for each question.

**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 Enrollment form to become certified in the NATPARA REMS Program.
Fax to: 1-844-NAT-REMS (628-7367)
Or email to: NATPARAREMS@NPSP.com

Reference ID: 3691249
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 Prescriber Enrollment Form at www.NATPARAREEMS.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)
  • Email to NATPARAREEMS@NPSP.com