

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125511Orig1s000

REMS

Initial REMS Approval: 01/2015

BLA 125511

NATPARA[®] (parathyroid hormone) for injection
Recombinant human parathyroid hormone (1-84)

NPS Pharmaceuticals

550 Hills Drive

Bedminster, NJ 07921

Telephone: 908-450-5300

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the NATPARA REMS Program is to mitigate the potential risk of osteosarcoma associated with NATPARA by:

- a. ensuring that prescribers are educated on the following:
 - potential risk of osteosarcoma associated with the use of NATPARA
 - appropriate patient selection
 - safe-use conditions required for prescribing NATPARA
- b. ensuring that NATPARA is dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

II. REMS Elements

A. Elements to Assure Safe Use (ETASU)

1. Healthcare providers who prescribe NATPARA are specially certified.

- a. To become specially certified to prescribe NATPARA in the NATPARA REMS Program, healthcare providers must:
 - i. Review the Prescribing Information for NATPARA.
 - ii. Review the *NATPARA REMS Program: An Introduction*.
 - iii. Review and successfully complete the *NATPARA REMS Training Module for Prescribers* including the *Knowledge Assessment* section.
 - iv. Enroll in the NATPARA REMS Program by completing, signing and sending the *NATPARA REMS Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center by fax at 844-NAT-REMS (628-7367) or email at NATPARAREMS@NPSP.COM.
 - v. Agree on the *NATPARA REMS Prescriber Enrollment Form* to:
 - 1) Review the *NATPARA Patient Brochure* with each patient to inform patients about the appropriate use and risks associated with NATPARA, and provide the patient a copy.
 - 2) Complete and sign the *NATPARA REMS Patient-Prescriber Acknowledgment Form* for each patient receiving a prescription for NATPARA. The prescriber will send a copy of the signed *NATPARA REMS Patient-Prescriber Acknowledgment Form* to the NATPARA REMS Program Coordinating Center by fax at 844-NAT-REMS (628-7367) or email at NATPARAREMS@NPSP.COM and will store a copy of the form in the patient's record.
- b. NPS Pharmaceuticals will:
 - i. Ensure that healthcare providers who prescribe NATPARA are specially certified, in accordance with the requirements described above.
 - ii. Ensure that prescriber certification process can be completed by sending the *Knowledge Assessment* and enrollment to the NATPARA REMS Program Coordinating Center via fax 844-NAT-REMS (628-

7367) or by emailing the NATPARA REMS Program Coordinating Center (NATPARAREMS@NPSP.com).

- iii. Ensure that prescribers are notified when they have been certified by the NATPARA REMS Program.
- iv. Maintain a validated, secure database of prescribers who are certified to prescribe NATPARA in the NATPARA REMS Program.
- v. Ensure that prescribers meet the REMS certification requirements and may de-certify prescribers who do not maintain compliance with prescriber certification requirements.
- vi. Provide the *NATPARA REMS Program: An Introduction* information sheet, *NATPARA REMS Training Module for Prescribers*, *NATPARA REMS Prescriber Enrollment Form*, *NATPARA Patient Brochure*, *NATPARA REMS Patient-Prescriber Acknowledgment Form*, and the Prescribing Information to prescribers who (1) attempt to prescribe NATPARA and are not yet certified, or (2) inquire about how to become certified.
- vii. Ensure that REMS materials are available on the *NATPARA REMS Website* (www.NATPARAREMS.com) or by calling the NATPARA REMS Coordinating Center at (855) 628-7272.

The following materials are part of the NATPARA REMS Program and are appended:

- *NATPARA REMS Program: An Introduction*
- *NATPARA REMS Training Module for Prescribers*
- *NATPARA REMS Prescriber Enrollment Form*
- *NATPARA Patient Brochure*
- *NATPARA REMS Patient-Prescriber Acknowledgment Form*

2. Pharmacies that dispense NATPARA are specially certified.

- a. To become specially certified to dispense NATPARA in the NATPARA REMS Program, pharmacies must:

- i. Designate an authorized representative to complete the certification process on behalf of the pharmacy.
- ii. Ensure the authorized representative will oversee implementation and compliance with the NATPARA REMS Program requirements by:
 - 1) Reviewing the Prescribing Information for NATPARA.
 - 2) Reviewing the *NATPARA REMS Program: An Introduction*.
 - 3) Reviewing and successfully completing the *NATPARA REMS Training Module for Pharmacy Representatives*, including the *Knowledge Assessment* section.
 - 4) Completing the *REMS Pharmacy Enrollment Form* and submitting to the NATPARA REMS Coordinating Center by fax at 844-NAT-REMS (628-7367) or email at NATPARAREMS@NPSP.COM.
 - 5) Ensuring that all relevant staff involved in the dispensing of NATPARA are trained on the NATPARA REMS Program requirements as described in the *NATPARA REMS Training Module for Pharmacy Representatives*.
 - 6) Putting processes and procedures in place, and following such processes and procedures, to ensure the following requirements are completed prior to dispensing NATPARA:
 - a) Verifying that the prescriber is certified in the NATPARA REMS Program by reviewing the prescriber's information against a list of REMs certified prescribers sent from the NATPARA REMS Program Coordinating Center.
 - b) Verifying that a *NATPARA REMS Patient-Prescriber Acknowledgment Form* has been completed and submitted by verifying that the patient and the prescriber are included in a list of REMS-approved patients and prescribers available through the NATPARA REMS Program Coordinating Center.
- iii. Agree to be audited by NPS Pharmaceuticals, FDA, or a third party to ensure that all training, processes and procedures are in place and

- are being followed for the NATPARA REMS Program and appropriate documentation is maintained and available upon request.
- iv. Provide prescription data to the NATPARA REMS Program.
 - v. Refrain from reselling or transferring NATPARA to other pharmacies or distributors.
 - vi. Recertify in the NATPARA REMS Program if the pharmacy designates someone else as the authorized representative.
- b. A Pharmacy must dispense NATAPRA to a patient only after verifying a *NATPARA REMS Patient-Prescriber Acknowledgment Form* is on record and the prescribing healthcare provider is certified in the NATPARA REMS Program.
- c. NPS Pharmaceuticals will:
- i. Ensure that NATPARA is dispensed only by pharmacies that are specially certified.
 - ii. Ensure that pharmacy certification process can be completed by sending the *Knowledge Assessment* and enrollment to the NATPARA REMS Program Coordinating Center via fax (844-628-7367) or email at NATPARAREMS@NPSP.COM.
 - iii. Ensure that the authorized representative is notified when the pharmacy has been certified by the NATPARA REMS Program.
 - iv. Ensure that certified pharmacies are provided a list daily of certified prescribers and records documenting receipt of *NATPARA REMS Patient-Prescriber Acknowledgment Forms*.
 - v. Verify every 2 years that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, the pharmacy will be required to re-certify with a new appointed authorized representative.
 - vi. Provide the *NATPARA REMS Program: An Introduction*, *NATPARA REMS Training Module for Pharmacy Representatives*, *NATPARA*

REMS Pharmacy Enrollment Form, and the Prescribing Information to pharmacies that inquire about how to become certified.

The following materials are part of the NATPARA REMS Program and are appended:

- *NATPARA REMS Training Module for Pharmacy Representatives*
- *NATPARA REMS Pharmacy Enrollment Form*

3. NATPARA will be dispensed to patients with evidence or other documentation of safe-use conditions.

- a. NATPARA will be dispensed only to patients who have been counseled about the potential risk of osteosarcoma and completed and signed a *NATPARA REMS Patient-Prescriber Acknowledgment Form*.
- b. NPS Pharmaceuticals will:
 - i. Ensure that the certified prescriber is able to submit the completed *NATPARA REMS Patient-Prescriber Acknowledgment Form* to the NATPARA REMS Program Coordinating Center by fax at 844-NAT-REMS (628-7367) or by email at NATPARAREMS@NPSP.COM.
 - ii. Ensure that the certified pharmacy is able to verify prior to dispensing that each patient prescribed NATPARA has completed and signed a *NATPARA REMS Patient-Prescriber Acknowledgment Form*.

B. Implementation System

1. NPS Pharmaceuticals will ensure that NATPARA is distributed to and dispensed only by certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute NATPARA to certified pharmacies comply with the program requirements for wholesalers/distributors. In order for a wholesaler/distributor to distribute NATPARA, the wholesaler/distributor must:

- i. Put processes and procedures in place to verify, prior to distributing NATPARA, that the pharmacies are certified.
 - ii. Train all relevant staff on the NATPARA REMS Program requirements.
 - iii. Agree to be audited by NPS Pharmaceuticals, FDA, or a third party to ensure that all processes and procedures are in place and are being followed for the NATPARA REMS Program and appropriate documentation is maintained and available upon request.
 - iv. Provide distribution data to the NATPARA REMS Program.
2. Ensuring that wholesalers/distributors maintain distribution records of all shipments of NATPARA to certified pharmacies and provide the data to the NATPARA REMS Program Coordinating Center. NPS Pharmaceuticals will send the distributors/wholesalers a list of certified pharmacies every month or anytime there is a new certified pharmacy added.
3. NPS Pharmaceuticals will monitor distribution data and audit the wholesalers/distributors within 180 days after the first shipment of NATPARA by wholesaler/distributor to ensure that all processes and procedures are in place and functioning to support the requirements of the NATPARA REMS Program. Corrective action will be instituted by NPS Pharmaceuticals if noncompliance is identified.
4. NPS Pharmaceuticals will send confirmation of certification to each certified pharmacy.
5. NPS Pharmaceuticals will monitor and audit certified pharmacies within 30 days after the pharmacy is certified to ensure that all processes and procedures are in place and functioning to support the requirements of the NATPARA REMS Program. Corrective action will be instituted by NPS Pharmaceuticals if noncompliance is identified. The certified pharmacy will also be included in NPS Pharmaceuticals' ongoing annual audit plan.

6. NPS Pharmaceuticals will maintain a validated, secure database of pharmacies that are certified to dispense NATPARA in the NATPARA REMS Program.
7. NPS Pharmaceuticals will maintain adequate records of NATPARA distribution/dispensing, certified prescribers, pharmacies, health care settings, distributors/wholesalers, and patients, to meet REMS requirements.
8. NPS Pharmaceuticals will ensure that the REMS requirements are met and may de-certify pharmacies that do not maintain compliance with pharmacy certification requirements.
9. NPS Pharmaceuticals will maintain a NATPARA REMS Program Coordinating Center with a call center to support patients, prescribers, and pharmacies in interfacing with the NATPARA REMS Program.
 - iii. NPS Pharmaceuticals will ensure that all materials listed in or appended to the NATPARA REMS Program are available through the NATPARA REMS Website at www.NATPARAREMS.com or from the NATPARA REMS Program Coordinating Center at (855) 628-7272.
10. NPS Pharmaceuticals will take reasonable steps to improve implementation of and compliance with the requirements in the NATPARA REMS Program based on monitoring and evaluation of the NATPARA REMS Program.
11. NPS REMS website for healthcare professionals (www.NATPARAREMS.com) will continue for the duration of the REMS. The NATPARA REMS website will include the option to print versions of the NATPARA REMS materials. The NATPARA website for healthcare professionals will include a prominent REMS-specific link to NATPARA REMS website.

C. Timetable for Submission of Assessments

NPS Pharmaceuticals will submit REMS Assessments to FDA at 6 months, 12 months, and annually thereafter from the date of initial approval of the NATPARA REMS. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. NPS Pharmaceuticals will submit each assessment so that it will be received by FDA on or before the due date.

NATPARA[®] (parathyroid hormone) for injection

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

PRESCRIBER TRAINING MODULE



Contents



Introduction

NATPARA[®] (parathyroid hormone) for injection

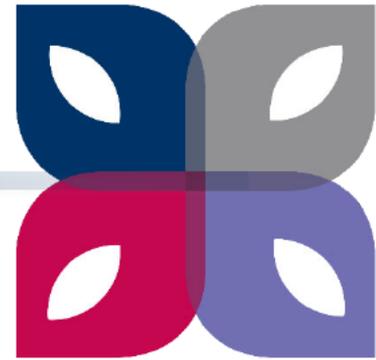
- Indication
- **Boxed Warning:** Potential Risk of Osteosarcoma
- Appropriate Patient Selection

NATPARA REMS Program Information

Questions about the NATPARA REMS Program

Knowledge Assessment

Introduction



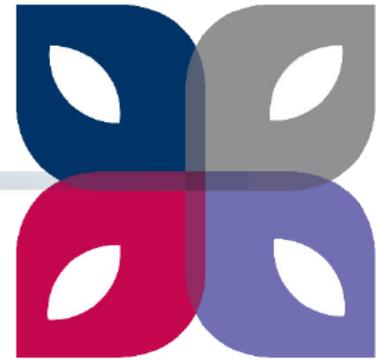
Introduction



- 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

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 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.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
 - Email to NATPARAREMS@NPSP.COM

Patient Counseling on Benefit/Risk Profile



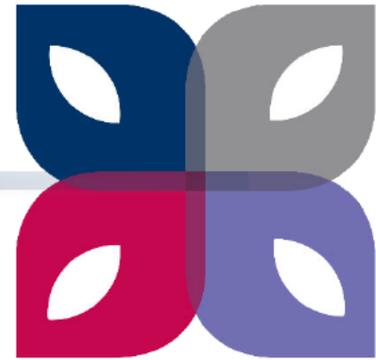
- Prescriber must counsel patients on the benefit/risk profile of NATPARA
 - The NATPARA *REMS Patient-Prescriber Acknowledgment Form* contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients
 - Provide patients with copies of the NATPARA *Patient Brochure*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

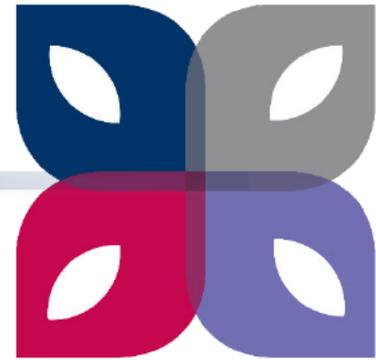


Questions about the NATPARA REMS Program



- 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.**

Knowledge Assessment



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

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.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)
 - Email to NATPARAREMS@NPSP.com

NATPARA REMS Program: Prescriber Enrollment Form

NATPARA® (parathyroid hormone) for injection is only available through the NATPARA Risk Evaluation and Mitigation Strategy (REMS) Program. In order to prescribe NATPARA, a prescriber must:

1. Review the Prescribing Information, the NATPARA REMS Program: An Introduction information sheet, the NATPARA REMS Training Module for Prescribers, and successfully complete the Knowledge Assessment.
2. Complete this one-time NATPARA REMS Prescriber Enrollment Form.
3. Complete and submit a NATPARA REMS Patient-Prescriber Acknowledgment Form prior to initiation of therapy for each patient.

Complete this enrollment form and submit it to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and e-mail it to NATPARAREMS@npsp.com. Please print. All information is required.

Prescriber Information

Name (first, middle, last): _____ Credentials: MD DO NP PA Other: _____

Name of Institution/Practice Name: _____

Practice Setting: Hospital-Based Practice Private/Group Practice

Practice Address: _____ Physician Specialty (Board Certification):

City: _____ State: _____ Zip Code: _____ Endocrinology Internal Medicine

Preferred Method of Contact: Mail E-mail E-mail Address: _____ Family Medicine

Office Phone Number: _____ Mobile Phone Number: _____ Office Fax Number: _____ Other [please specify]: _____

Primary State License Number/State of Issue: _____

National Provider Identification (NPI) Number: _____

Prescriber Attestation

By signing this form I attest that:

- I understand that 1) NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism 2) NATPARA is not a parathyroid hormone replacement and 3) 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
- I understand there is a potential risk of osteosarcoma associated with NATPARA. NATPARA causes an increase in the incidence of osteosarcoma in rats. The increase in osteosarcoma in rats is dependent on NATPARA dose and treatment duration
- I understand that NATPARA is only available through the NATPARA REMS Program and that I must comply with the program requirements in order to prescribe NATPARA
- I have reviewed the Prescribing Information, the NATPARA REMS Program: An Introduction and NATPARA REMS Training Module for Prescribers and answered all questions included in the Knowledge Assessment
- I understand that I must counsel my patients on the benefits and risks of NATPARA treatment, sign and submit the NATPARA REMS Patient-Prescriber Acknowledgment Form, and provide a copy of the NATPARA Patient Brochure and NATPARA REMS Patient-Prescriber Acknowledgment Form to my patients prior to initiation of therapy
- I agree that NPS Pharmaceuticals, its agents, and contractors, such as the pharmacy, may contact me via phone, mail, or e-mail to survey me on the effectiveness of the program requirements for NATPARA REMS

Prescriber Signature: _____ Date: _____ (MM/DD/YY)

Print Name: _____

**If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com**



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What Is the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and it is required by the FDA to ensure that the benefits of the drug outweigh its risks. NATPARA® (parathyroid hormone) for injection is available only under a restricted program called the NATPARA REMS Program because of the potential risk of osteosarcoma.

NATPARA REMS Program Requirements

- Certification of prescribers of NATPARA
- Patient counseling on the benefits and risks of NATPARA and completion of a NATPARA *REMS Patient-Prescriber Acknowledgment Form* for each patient
- Only certified pharmacies can dispense NATPARA

Prescriber Certification

1. Review the Prescribing Information and NATPARA *REMS Program: An Introduction*.
2. Successfully complete the NATPARA *REMS Training Module for Prescribers*, including the Knowledge Assessment.
3. Complete and sign the NATPARA *REMS Prescriber Enrollment Form*.

Patient Counseling and Patient-Prescriber Acknowledgment Form

- Counsel patients on appropriate use and the benefits and risks of NATPARA
- Download the NATPARA *REMS Patient Brochure* and NATPARA *REMS Patient-Prescriber Acknowledgment Form* at www.NATPARAREMS.com or request copies by calling 1-855-NATPARA
- Complete the NATPARA *REMS Patient-Prescriber Acknowledgment Form* and NATPARA prescription. Send both to the NATPARA REMS Program Coordinating Center via fax at 1-844-NAT-REMS (628-7367) or scan and e-mail to NATPARAREMS@npsp.com
- Provide patient with a copy of the NATPARA *Patient Brochure* and NATPARA *REMS Patient-Prescriber Acknowledgment Form*

Pharmacy Certification

Pharmacies must designate an authorized Pharmacy Representative who will complete the certification process on behalf of the pharmacy and:

1. Review the Prescribing Information and NATPARA *REMS Program: An Introduction*.
2. Successfully complete the NATPARA *REMS Training Module for Pharmacy Representatives*, including the Knowledge Assessment.
3. Complete and sign the NATPARA *REMS Pharmacy Enrollment Form*.
4. Implement the necessary staff training and processes to comply with the NATPARA REMS Program requirements including:
 - Receiving the prescription from the REMS Program Coordinating Center
 - Verification that prescriber is certified in the NATPARA REMS Program
 - Verification that a NATPARA *REMS Patient-Prescriber Acknowledgment Form* is on record for patient and prescriber
 - Contacting the patient to arrange the date to ship NATPARA once the prescription is filled

Visit www.NATPARAREMS.com to access training materials and enrollment forms. Or call 1-855-NATPARA.

If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com

NATPARA[®] (parathyroid hormone) for injection

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

TRAINING MODULE FOR PHARMACY
REPRESENTATIVES



Contents



Introduction

NATPARA® (parathyroid hormone) for injection

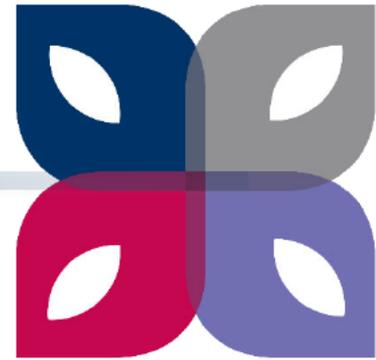
- Indication
- **Boxed Warning:** Potential Risk of Osteosarcoma
- Appropriate Patient Selection

NATPARA REMS Program Information

Questions about the NATPARA REMS Program

Knowledge Assessment

Introduction



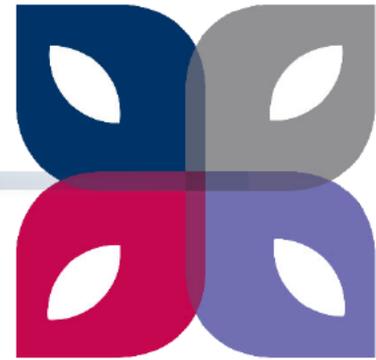
Introduction



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NATPARA[®]

(parathyroid hormone) for injection



Indication



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 - 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

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:
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 - 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 Patient-Prescriber Acknowledgment Form* for each patient
- **Only certified pharmacies may dispense NATPARA**
 - Verification of prescriber certification before dispensing NATPARA
 - Verification of NATPARA *REMS 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 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 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 Training Module for Pharmacy Representatives
2. Find the NATPARA REMS 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
 - Email to NATPARAREMS@NPSP.COM

Pharmacy Representative Responsibilities



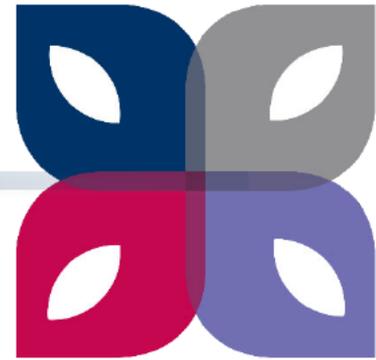
- Ensure all relevant staff involved in dispensing of NATPARA are trained on the NATPARA REMS Program requirements as described in the NATPARA *REMS Training Module for Pharmacy Representatives*
- Put processes and procedures in place to ensure the following verifications and safe-use conditions are met prior to dispensing NATPARA:
 - Receive the prescription from the REMS Program Coordinating Center
 - Verify that the prescriber is certified in the NATPARA REMS program
 - Verify that a NATPARA *REMS 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 NPS Pharmaceuticals — 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

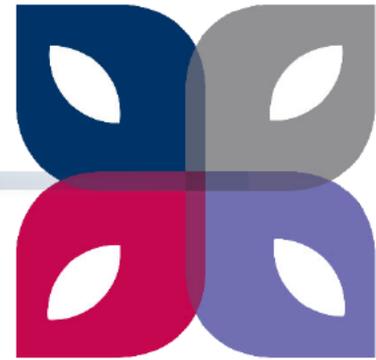


Questions about the NATPARA REMS Program



- 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

- 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.**

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 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.

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

Or email to: NATPARAREMS@NPSP.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* 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)
 - Email to NATPARAREMS@NPSP.com

NATPARA REMS Program: Pharmacy Enrollment Form

To become certified, the pharmacy must designate an authorized Pharmacy Representative to coordinate the setting's activities and assure compliance with the NATPARA® Risk Evaluation and Mitigation Strategy (REMS) Program.

INSTRUCTIONS:

Fax completed form to the NATPARA REMS Program Coordinating Center at 1-844-NAT-REMS (628-7367) or scan form and e-mail it to NATPARAREMS@nps.com. You will receive an enrollment confirmation within 2 business days after your form is received.

NATPARA is only available through the NATPARA REMS Program.

Because of the risk of osteosarcoma associated with NATPARA, only certified pharmacies may dispense NATPARA.

Authorized Pharmacy Representative Responsibilities

As the authorized Pharmacy Representative designated by my pharmacy to coordinate the activities of the NATPARA REMS Program, I agree to comply with the following program requirements:

1. Review the Prescribing Information and the NATPARA REMS Program: *An Introduction* information sheet.
2. Review the NATPARA REMS Training Module for Pharmacy Representatives, and answer all questions in the Knowledge Assessment.
3. Ensure all relevant staff involved in dispensing NATPARA are trained on the NATPARA REMS Program requirements as described in the NATPARA REMS Training Module for Pharmacy Representatives.
4. Put processes and procedures in place to ensure the following verifications and safe use conditions are met prior to dispensing NATPARA:
 - Verify that the prescriber is certified in the NATPARA REMS Program by reviewing the prescriber's information against a list of REMS certified prescribers sent from the NATPARA REMS Program Coordinating Center
 - Verify that a NATPARA REMS Patient-Prescriber Acknowledgment Form has been completed and submitted by verifying that the patient and prescriber are included in a list of REMS approved patients and prescribers available through the NATPARA REMS Program Coordinating Center
5. Make available to NPS Pharmaceuticals, and/or a designated third party of FDA, documentation to verify understanding of, and adherence to, the requirements of the NATPARA REMS Program.

Please print. All information is required.

Authorized Pharmacy Representative

Name (first, middle, last): _____

Pharmacy Name: _____

Pharmacy Address: _____

City: _____ State: _____ Zip Code: _____ Preferred Method of Contact: Mail E-mail

E-mail Address: _____ Office Phone Number: _____ Office Fax Number: _____

Signature: _____ Date: _____

Authorized Pharmacy Representative

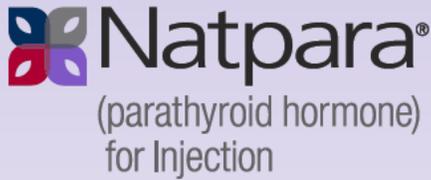
(MM/DD/YY)

If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com



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NATPARA PATIENT BROCHURE

What you need to know about NATPARA

What is NATPARA?

NATPARA is a parathyroid hormone (PTH) used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low PTH blood levels (hypoparathyroidism).

What is the most serious risk of NATPARA?

- Possible risk of bone cancer
- During animal drug testing, the medicine in NATPARA caused some rats to develop bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer
- It is not known if people who take NATPARA will have a higher chance of getting bone cancer
- Because of the potential risk of bone cancer, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone

What are the signs and symptoms of bone cancer?

- Pain in any areas of your body that does not go away
- Any new or unusual lumps or swelling under your skin that is tender to touch

Tell your doctor right away if you have any of these signs or symptoms.

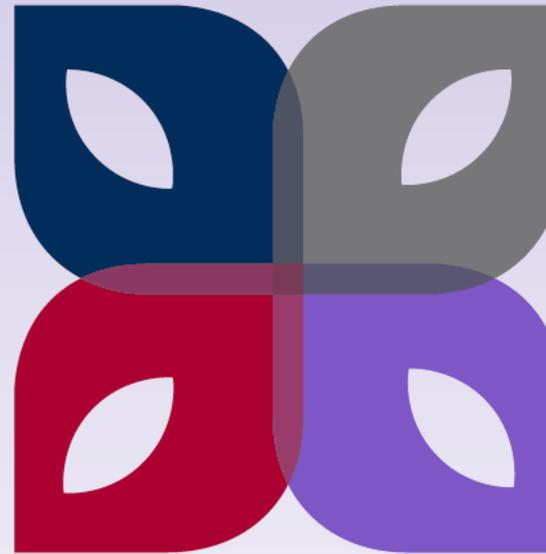
The NATPARA REMS Program

- Because of the possible risk of bone cancer, NATPARA is only available through a special program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
- Your doctor will discuss the benefits and risks of NATPARA with you
- You and your doctor will sign the NATPARA *REMS Patient-Prescriber Acknowledgment Form*. You must sign this form in order to receive NATPARA

How do I receive NATPARA?

NATPARA is only available through a REMS Certified Pharmacy. The NATPARA REMS Program Coordinating Center will call you to tell you the name and phone number of the certified pharmacy that will fill your NATPARA prescription. The certified pharmacy will call you to arrange the date to ship NATPARA to you. Call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA if you need assistance with your prescription.

This brochure only discusses the most serious risk of NATPARA and the NATPARA REMS Program. For more safety information about NATPARA please see the NATPARA Medication Guide available at www.NATPARAREMS.com.



NATPARA REMS: Patient-Prescriber Acknowledgment Form

Instructions for Prescribers

1. Counsel the patient on the benefits and risks of NATPARA.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Send the completed form and the patient's prescription to the NATPARA REMS Program Coordinating Center by fax to 1-844-NAT-REMS (628-7367) or e-mail to NATPARAREMS@npsp.com

Instructions for Patients

1. NATPARA is available only through a special program called the NATPARA REMS Program.
2. This form must be completed before you can receive NATPARA® (parathyroid hormone) for injection.
3. Your prescriber will help you complete this form and will give you a copy.
4. The NPS REMS Program Coordinating Center will help you find a certified pharmacy to fill your NATPARA prescription.

Patient Demographic Information (Please Print)

Gender*: Male Female Age*: _____

Patient Acknowledgment

By signing this form, I acknowledge that:

- I have received, read, and understand the information in the NATPARA *Patient Brochure*.
- My doctor reviewed with me the benefits and risks of treatment with NATPARA listed below and answered all my questions or concerns about my treatment with NATPARA.
- I understand that I should tell my doctor right away if I have any of the following signs or symptoms that could be associated with osteosarcoma:
 - pain in any areas of my body that does not go away
 - any new or unusual lumps or swelling under my skin that is tender to touch

Benefits:

- NATPARA is a parathyroid hormone (PTH). It is used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low PTH blood levels (hypoparathyroidism).

Risks:

- During animal drug testing, the medicine in NATPARA caused some rats to develop a type of bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer.
- It is not known if people who take NATPARA have a higher chance of getting bone cancer.
- Because of the potential risk of bone cancer, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone.

Written Permission to Share Information

- I give permission to my healthcare provider to share this form with NPS Pharmaceuticals and their Contractors to use and share my personal health information for the purposes of coordinating the dispensing of NATPARA, administering the NATPARA REMS Program, and releasing my personal health information to the Food and Drug Administration (FDA) as necessary.
- My permission lasts until the Program ends. I can cancel my permission at any time by providing written notice to my healthcare provider.

Patient/Legal Representative Signature*: _____ Date*: _____
Printed Name*: _____ (MM/DD/YY)

Prescriber Acknowledgment

I acknowledge that prior to prescribing NATPARA:

- I counseled the patient on the benefits and risks of NATPARA by reviewing the NATPARA *Patient Brochure* and the NATPARA REMS *Patient-Prescriber Acknowledgment Form*.
- I discussed all concerns and answered any questions raised by the patient or patient representative.
- The patient or patient representative signed this *Acknowledgment Form* and I provided a copy of the signed *Acknowledgment Form* to the patient.

Prescriber NPI*: _____

Signature of Prescriber*: _____

Printed Name*: _____

Date*: _____
(MM/DD/YY)

*Indicates mandatory field.

Please fax this completed form to the NATPARA REMS Program at 1-844-NAT-REMS.



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NATPARA REMS Program Prescriber Certification

Prescriber certification is required to prescribe NATPARA. To become certified, prescribers must:



1. Review the *Prescribing Information* and the *NATPARA REMS Program: An Introduction* information sheet.
2. Review the *NATPARA REMS Training Module for Prescribers* and successfully complete the Knowledge Assessment.
3. Complete the one-time *NATPARA REMS Prescriber Enrollment Form*.
4. Submit the Knowledge Assessment and the *NATPARA REMS Prescriber Enrollment Form*.
 - Fax to 1-844-NAT-REMS (628-7367) or
 - Scan and e-mail to NATPARAREMS@nps.com

A confirmation of your certification in the NATPARA REMS Program will be sent to you so you can begin to prescribe NATPARA.

Before initiating treatment, prescribers must also counsel patients on the appropriate use and the benefit and risks of NATPARA. To complete the NATPARA REMS Program requirements for prescribing NATPARA:



- Download the *NATPARA REMS Patient Brochure* and *NATPARA REMS Patient-Prescriber Acknowledgment Form*
- Complete the *NATPARA REMS Patient-Prescriber Acknowledgment Form*
- Send the patient's prescription and the *NATPARA REMS Patient-Prescriber Acknowledgment Form* by
 - Fax to 1-844-NAT-REMS (628-7367) or
 - Scan and e-mail to NATPARAREMS@nps.com
- Provide patient with a copy of the *NATPARA Patient Brochure* and *NATPARA REMS Patient-Prescriber Acknowledgment Form*

If you have any questions, contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA.

MATERIALS TO DOWNLOAD

For Prescribers

- [NATPARA Prescribing Information](#)
- [NATPARA REMS Program: An Introduction Training Module and Assessment for Prescribers](#)
- [Prescriber Enrollment Form](#)
- [Patient-Prescriber Acknowledgment Form and NATPARA Patient Brochure](#)

NATPARA REMS Program Pharmacy Certification

To become certified, pharmacies must designate an authorized Pharmacy Representative to coordinate the setting's activities and assure compliance. The designated Pharmacy Representative must complete the following steps for certification:



1. Review the *Prescribing Information* and the *NATPARA REMS Program: An Introduction* information sheet.

2. Review the *NATPARA REMS Training Module for Pharmacy Representatives* and successfully complete the Knowledge Assessment.



3. Complete and sign the *NATPARA REMS Pharmacy Enrollment Form*.

4. Submit the Knowledge Assessment and the *NATPARA REMS Pharmacy Enrollment Form*.

- Fax to 1-844-NAT-REMS (628-7367) or
- Scan and e-mail to NATPARAREMS@npsp.com

A confirmation of your certification in the NATPARA REMS Program will be sent to the pharmacy so you can begin to distribute NATPARA.

5. Ensure all relevant staff involved in dispensing NATPARA are trained on the NATPARA REMS Program requirements as described in the *NATPARA REMS Training Module for Pharmacy Representatives*.

6. Put processes and procedures in place to ensure the following verifications and safe use conditions are met prior to dispensing NATPARA:

- Verifying that the prescriber is certified in the NATPARA REMS Program by reviewing the prescriber's information against a list of REMS-certified prescribers sent from the NATPARA REMS Program Coordinating Center
- Verifying that a *NATPARA REMS Patient-Prescriber Acknowledgment Form* has been completed and submitted for the corresponding patient and prescriber by reviewing the patient and prescriber against a list of REMS-approved patients and prescribers available through the NATPARA REMS Program Coordinating Center

7. Make available to NPS Pharmaceuticals, Inc. and/or a designated third-party of FDA, documentation to verify understanding of, and adherence to, the requirements of the NATPARA REMS Program.

8. Recertify in the NATPARA REMS Program if the pharmacy designates someone else as the authorized representative.

If you have any questions, contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA.

MATERIALS TO DOWNLOAD

For Pharmacies

[NATPARA Prescribing Information](#)

[NATPARA REMS Program: An Introduction Training Module and Assessment for Pharmacies](#)

[Pharmacy Enrollment Form](#)



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Prescriber
CertificationPharmacy
Certification

NATPARA REMS Program

(Risk Evaluation and Mitigation Strategy)

What is the NATPARA REMS Program?

A REMS Program is a strategy to manage known or potential serious risks associated with a drug product, and it is required by the FDA to ensure the benefits of a drug outweigh its risks. The NATPARA REMS Program informs prescribers, pharmacists, and patients about the potential risk of:

Osteosarcoma

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

Indication:

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

Because of 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.

NATPARA is not a parathyroid hormone replacement.

Program Requirements

NATPARA is only available through the NATPARA REMS Program. The requirements include:

For Prescribers

- **Certification** by completing training, including Knowledge Assessment, and enrollment into NATPARA REMS Program
- **Patient Counseling** on benefits and risks of NATPARA
- **Completion** of *Patient-Prescriber Acknowledgment Form* for each patient prior to initiation of treatment
- **Provide** patient with a copy of the completed *Patient-Prescriber Acknowledgment Form* and the NATPARA *Patient Brochure*

For Pharmacies

Pharmacies must designate an authorized Pharmacy Representative who will complete the certification process on behalf of the pharmacy:

- **Certification** by completing training, including Knowledge Assessment, and enrolling into the NATPARA REMS Program
- **Implementing** the necessary staff training and processes to comply with the NATPARA REMS Program requirements including:
 - **Verifying** that the prescriber is certified in NATPARA REMS Program
 - **Verifying** that a *Patient-Prescriber Acknowledgment Form* is on record for patient and prescriber

If you have any questions, contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA.



Prescriber Training
and Enrollment



Pharmacist Training
and Enrollment

MATERIALS TO DOWNLOAD

For Prescribers

- [NATPARA Prescribing Information](#)
- [NATPARA REMS Program: An Introduction Training Module and Assessment for Prescribers](#)
- [Prescriber Enrollment Form](#)
- [Patient-Prescriber Acknowledgment Form and NATPARA Patient Brochure](#)

For Pharmacies

- [NATPARA Prescribing Information](#)
- [NATPARA REMS Program: An Introduction Training Module and Assessment for Pharmacies](#)
- [Pharmacy Enrollment Form](#)



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