NATPARA REMS Program: 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 along with a copy of the NATPARA *REMS Program Patient Brochure*.
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@takeda.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 along with a copy of the NATPARA *REMS Program Patient Brochure*.
4. The NATPARA 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 *REMS Program 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 Takeda 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*:** _____
(MM/DD/YY)

Printed Name*: _____

Prescriber Acknowledgment

I acknowledge that prior to prescribing NATPARA:

- I counseled the patient on the benefits and risks of NATPARA by reviewing the NATPARA *REMS Program Patient Brochure* and the NATPARA *REMS Program: 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 NATPARA *REMS Program: Acknowledgment Form* and I provided a copy of the NATPARA *REMS Program Patient Brochure* and the signed NATPARA *REMS Program: Acknowledgment Form* to the patient.

Prescriber NPI*: _____

Signature of Prescriber*: _____

Printed Name*: _____

Date*: _____
(MM/DD/YY)

*Indicates mandatory field.

Please fax this completed form and the patient's prescription to the NATPARA REMS Program Coordinating Center at 1-844-NAT-REMS.

Takeda

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

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for Injection
25 • 50 • 75 • 100 mcg per dose strength

NATPARA REMS PROGRAM 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 Program: 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.

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