

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@shire.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 Shire 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 *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.



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