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

NATPARA REMS PROGRAM
Frequently Asked Questions (FAQ)

1 What is a Risk Evaluation and Mitigation Strategy (REMS)?

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug or biologic beyond product labeling; it is required by the FDA if necessary to ensure that the benefits of a drug or biologic outweigh its risks.

2 Why does NATPARA have a REMS Program?

FDA has determined that a REMS is necessary to ensure that the benefits of NATPARA outweigh the potential risk of osteosarcoma.

3 What is the goal of the NATPARA REMS Program?

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

- 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
- Ensuring that NATPARA is dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

4 What are the NATPARA REMS Program requirements?

The NATPARA REMS Program requirements are as follows:

- 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 counseled on the benefits and risks of NATPARA and after completion and submission of a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* for each patient

5 What do I need to do in order to prescribe NATPARA?

In order to prescribe NATPARA, you need to become certified and enroll in the NATPARA REMS Program. You can complete the certification and enrollment process directly online or through a paper-based process.

A. Online

- Visit www.NATPARAREMS.com
- Click on the "Prescriber Certification" tab for instructions
- You will be required to enter your National Provider Identifier (NPI) number and your name as it appears in the NPI registry in order to initiate the online process

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B. Paper-based

- Review the following:
  - NATPARA *Prescribing Information*
  - NATPARA *REMS Program: An Introduction*
  - NATPARA *REMS Program: Training Module for Prescribers*
- Successfully complete the Knowledge Assessment questions at the end of the training module (100% passing score required)
- Complete and sign the one-time NATPARA *REMS Program: Prescriber Enrollment Form*
- Submit both 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 two (2) business days (paper-based). 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).

6 What is the prescription process for NATPARA?

Once a prescriber is certified, the following steps must take place for a patient to receive NATPARA.

1. Complete the one-time NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* with each patient prior to initiation of therapy
2. Provide patients with a copy of the signed form and copy of the NATPARA *REMS Program Patient Brochure*
3. Submit the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* and prescription to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com
4. The NATPARA REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* is on record
5. 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
6. The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled

7 Can I become certified and enroll online?

Yes, visit www.NATPARAREMS.com and click on the "Prescriber Certification" tab for instructions. You will be required to enter your National Provider Identifier (NPI) number and your name as it appears in the NPI registry in order to initiate the online process.

8 Can I become certified over the phone?

No, you will need to complete the certification and enrollment either online at www.NATPARAREMS.com or through a paper-based process as described in Question 5.

9 How long does it take to become certified?

The time to review the required training materials varies among individuals, but the Knowledge Assessment consists of seven multiple-choice questions and can generally be completed within 10 minutes.

10 I entered my NPI (National Provider Identifier) number and name to become certified online, but I received a message that the information could not be verified. What does this mean, and what should I do?

This means that either:

- The information was entered incorrectly
- The information entered does not match the information in the national NPI registry database; the name entered must match the name you provided for your NPI
- You recently received your NPI, and the database has not been updated yet

If you experience difficulties with the online certification process, you may complete hard copies of the Knowledge Assessment and NATPARA *REMS Program: Prescriber Enrollment Form* and fax them to 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com. You may also call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) for assistance.

11 I am having some problems certifying online, what should I do?

If you experience difficulties with the online certification process, you may complete hard copies of the Knowledge Assessment and NATPARA *REMS Program: Prescriber Enrollment Form* and fax them to 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com. You may also call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) for assistance.

12 Can I become certified even if I do not plan to write a prescription for NATPARA right away?

Yes, you can become certified without writing a prescription for NATPARA.

Prior to writing a prescription for NATPARA, it is important to have reviewed the NATPARA *Prescribing Information*, NATPARA *REMS Program: An Introduction*, and NATPARA *REMS Program: Training Module for Prescribers* to be educated on:

- The potential risk of osteosarcoma associated with the use of NATPARA
- Appropriate patient selection
- The safe-use conditions required for prescribing NATPARA, including the need to counsel patients on the potential risk of osteosarcoma associated with the use of NATPARA and the need to complete and submit a one-time NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* for each patient

13 Do I lose my certification status if I do not prescribe NATPARA?

No, healthcare professionals remain certified as long as they are compliant with the REMS Program requirements.

14 I am in a group practice; can the practice become certified as a whole?

No, the NATPARA REMS Program requires that every individual prescriber be certified in order to prescribe. Visit www.NATPARAREMS.com to become certified, or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) for instructions on how to become certified.

15 I am temporarily covering for another physician who is already certified. Do I need to become certified in order to prescribe NATPARA for his/her patient?

Yes, certification is required for every prescriber of NATPARA. Visit www.NATPARAREMS.com to become certified or for instructions on how to become certified, or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272). In addition, you will need to complete and submit a one-time NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* with this patient.

16 I was referred a patient who was prescribed NATPARA from a certified prescriber. Do I need to become certified in order to prescribe and continue NATPARA treatment for this patient?

Yes, certification is required for every prescriber of NATPARA. Visit www.NATPARAREMS.com to become certified or for instructions on how to become certified, or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272). In addition, you will need to complete and submit a one-time NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* with this patient.

17 Can a nurse practitioner and/or physician assistant become certified?

Yes, any healthcare professional with a National Provider Identifier (NPI) and license to prescribe may become certified in the NATPARA REMS Program.

18 I moved my practice to a different state; do I need to recertify?

No, the NATPARA REMS Program requires prescribers to certify one time only through their NPI, regardless of their location.

19 Do I need to recertify on a regular basis?

No, the NATPARA REMS Program requires prescribers to certify one time only.

20 What do I need to counsel my patients on?

Each patient should be counseled on the appropriate use and benefits and risks of NATPARA by reviewing the NATPARA *REMS Program Patient Brochure* and completing the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form*.

Download these materials at www.NATPARAREMS.com or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) to receive copies.

21 Can the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* be electronically signed and submitted online?

No, the form needs to be manually signed by both the patient and prescriber and submitted to the NATPARA REMS Program Coordinating Center.

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

22 How often does a patient have to complete and sign a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form*?

The NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* should be completed once for each patient with their prescriber.

23 My patient signed a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* at a previous physician's office. Should he/she sign another if coming to my practice?

Yes, each prescriber should sign and submit a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* for each of their patients who will be prescribed NATPARA.

24 Can my patients go to their usual pharmacy to get their NATPARA prescription filled?

Only certified pharmacies can dispense NATPARA. 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.

25 My patient resides in multiple locations throughout the year. Can NATPARA be shipped to different locations?

Yes, once the prescription is filled, the certified pharmacy will contact the patient to arrange shipment.

26 How do I get copies of the NATPARA REMS Program materials?

Copies of materials can be downloaded at www.NATPARAREMS.com or obtained by calling the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272).

27 I have some questions/issues about the NATPARA REMS Program. Who do I call?

If you have any questions or issues regarding the NATPARA REMS Program, please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272).

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