NATPARA REMS Program: An Introduction

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 Program: Patient-Prescriber Acknowledgment Form* for each patient
- Only certified pharmacies can dispense NATPARA

Prescriber Certification

Prescriber certification and enrollment can be completed directly online at www.NATPARAREMS.com or through a paper-based process as follows:

1. Review the Prescribing Information, NATPARA *REMS Program: An Introduction*, and the NATPARA *REMS Program: Training module for Prescribers*.
2. Successfully complete and submit both the Knowledge Assessment section of the training module and the NATPARA *REMS Program: Prescriber Enrollment Form* via fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com.

Patient Counseling and Patient-Prescriber Acknowledgment Form

- Counsel patients on appropriate use and the benefits and risks of NATPARA
- Download the NATPARA *REMS Program: Patient Brochure* and NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* at www.NATPARAREMS.com or request copies by calling 1-855-NATPARA (628-7272)
- Complete the NATPARA *REMS Program: 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@shire.com
- Provide patient with a copy of the NATPARA *REMS Program: Patient Brochure* and NATPARA *REMS Program: 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 Program: Training Module for Pharmacy Representatives*, including the Knowledge Assessment.
3. Complete and sign the NATPARA *REMS Program: 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 NATPARA REMS Program Coordinating Center
   - Verification that prescriber is certified in the NATPARA REMS Program
   - Verification that a NATPARA *REMS Program: 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

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