Palynziq
REMS Program Overview

Risk Evaluation and Mitigation Strategy

This overview describes the requirements of the PALYNZIQ® (pegvaliase-pqpz) REMS and the responsibilities of prescribers, pharmacies, and patients.

If you have any questions regarding the PALYNZIQ REMS, please visit PALYNZIQREMS.com or call 1-855-758-REMS (1-855-758-7367).

Please see Prescribing Information, including BOXED WARNING, for additional Important Safety Information.
A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug continue to outweigh its risks.

Due to the risk of anaphylaxis, PALYNZIQ is available only through a restricted program called the PALYNZIQ REMS. PALYNZIQ may cause anaphylaxis; patients may experience an anaphylaxis episode immediately or at any time after an injection of PALYNZIQ. Episodes of anaphylaxis are more common at the beginning of treatment, but they can also occur anytime during treatment.

Anaphylaxis can be life-threatening and can occur quickly; inform your patients of the signs and symptoms, the appropriate use (when and how to use) auto-injectable epinephrine, and when to seek immediate medical care.
How Does the PALYNZIQ REMS Work?

**Before Prescribing/Dispensing PALYNZIQ**
- Prescriber certification

**Before starting PALYNZIQ for each Patient**
- Counsel and enroll patient and prescribe auto-injectable epinephrine

**While on PALYNZIQ Treatment for Each Patient**
- Assess for anaphylaxis episodes and patient’s epinephrine supply
  - Before dispensing, verify prescriber is certified and patient is authorized to receive PALYNZIQ
  - Before dispensing each dose, verify the patient has auto-injectable epinephrine

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**What are the Requirements of the PALYNZIQ REMS?**

In order to receive PALYNZIQ, prescribers, pharmacies, and patients must comply with the requirements of the PALYNZIQ REMS.

**Prescriber**
- **To prescribe PALYNZIQ:**
  1. **Become certified** by completing a one-time certification process
  2. As you start patients on PALYNZIQ, **counsel and enroll** them into the PALYNZIQ REMS and complete the prescription for PALYNZIQ and auto-injectable epinephrine

**Pharmacy**
- **To dispense PALYNZIQ:**
  1. Designate an authorized representative, become certified, and **recertify** if there is a change in the authorized representative
  2. **Train** staff and comply with REMS requirements
  3. Before dispensing PALYNZIQ, **verify** prescriber is certified and patient is authorized to receive PALYNZIQ and patient has auto-injectable epinephrine

**Patient**
- **To receive PALYNZIQ:**
  1. **Understand the risks** associated with PALYNZIQ
  2. **Enroll** in the PALYNZIQ REMS by completing the Patient Enrollment Form with your doctor
  3. **Fill** your prescription for auto-injectable epinephrine and carry it with you at all times

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*PALYNZIQ is not available to all pharmacies. If you have any questions about the PALYNZIQ REMS or how to obtain PALYNZIQ, call 1-855-758-REMS (1-855-758-7367).*
Review the following educational materials on PALYNZIQ to understand the risks of anaphylaxis and the need for auto-injectable epinephrine, and the PALYNZIQ REMS:

• Prescribing Information
• Prescriber Guide
• REMS Program Overview

Complete and submit using the submission details at the end of this document:

• Prescriber Knowledge Assessment
• Prescriber Enrollment Form

Once completed, the PALYNZIQ REMS will notify you that you are certified to prescribe PALYNZIQ

First, become certified.

1. Designate an authorized representative for the pharmacy. He or she will need to review the REMS Program Overview and will oversee implementation and ensure compliance with the PALYNZIQ REMS requirements.

2. Have the authorized representative complete and submit the Pharmacy Enrollment Form by fax.
   - Once this step is completed, the PALYNZIQ REMS will contact you to complete certification.
   - Dispensing of PALYNZIQ is limited to a small number of contracted pharmacies that will be certified.

3. Have the authorized representative ensure that all relevant staff involved in dispensing of PALYNZIQ are trained on the PALYNZIQ REMS requirements and that a record of training is maintained by the pharmacy.

Once you are certified, enroll your patients.

1. Counsel your patient about the risks associated with PALYNZIQ, including anaphylaxis and the need for auto-injectable epinephrine and share the resources below:
   - Patient Guide: What You Need to Know
   - Safety Video
   - Wallet Card

2. Submit a completed Patient Enrollment Form to the PALYNZIQ REMS. Provide a completed copy of the form to the patient and retain a copy in the patient’s records.

3. Prescribe auto-injectable epinephrine and instruct the patient on when and how to use it.

4. Assess the patient’s need for an adult observer and premedications as described in the Prescriber Guide.

5. Report any anaphylaxis episodes to the PALYNZIQ REMS. You may be contacted for more information about these episodes.

6. Assess the patient’s supply of auto-injectable epinephrine and provide the patient with a prescription for auto-injectable epinephrine refills as necessary.

7. Inform the PALYNZIQ REMS if a patient is no longer under your care or has discontinued PALYNZIQ.

When dispensing PALYNZIQ:

1. Before dispensing PALYNZIQ, verify that the prescriber is certified and the patient is authorized to receive PALYNZIQ by accessing the PALYNZIQ REMS Portal or by calling the PALYNZIQ REMS.

2. Confirm and document that the patient has auto-injectable epinephrine.

3. Report any anaphylaxis episodes to the PALYNZIQ REMS. You may be contacted for more information about these episodes.

4. Maintain appropriate documentation that all processes and procedures are in place and are being followed so that it can be provided upon request to BioMarin or a third party acting on behalf of BioMarin.

5. Recertify in the PALYNZIQ REMS if a new authorized representative is designated by completing and submitting the Pharmacy Enrollment Form.

The completed forms should be submitted to the PALYNZIQ REMS online, using the PALYNZIQ REMS Portal at PALYNZIQREMS.com, via fax to 1-866-713-8421, or by mail to 200 Pinecrest Plaza, Morgantown WV 26505.

Ensure compliance with REMS Requirements

When dispensing PALYNZIQ:

1. Before dispensing PALYNZIQ, verify that the prescriber is certified and the patient is authorized to receive PALYNZIQ by accessing the PALYNZIQ REMS Portal or by calling the PALYNZIQ REMS.

2. Confirm and document that the patient has auto-injectable epinephrine.

3. Report any anaphylaxis episodes to the PALYNZIQ REMS. You may be contacted for more information about these episodes.

4. Maintain appropriate documentation that all processes and procedures are in place and are being followed so that it can be provided upon request to BioMarin or a third party acting on behalf of BioMarin.

5. Recertify in the PALYNZIQ REMS if a new authorized representative is designated by completing and submitting the Pharmacy Enrollment Form.

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Before starting PALYNZIQ:

1. Discuss with your doctor and understand:
   - The risks associated with PALYNZIQ, including anaphylaxis
   - The need for (including how and when to use) an auto-injectable epinephrine

2. Receive and read the:
   - Patient Guide: What You Need to Know
   - Wallet Card (fill in your name and your doctor’s information)

3. Watch the Safety Video

4. Complete the Patient Enrollment Form with your doctor

5. Receive and fill a prescription for auto-injectable epinephrine

After starting PALYNZIQ:

1. Carry auto-injectable epinephrine with you at all times

2. Inform your healthcare providers if you have any signs or symptoms of a severe allergic reaction (anaphylaxis) after receiving PALYNZIQ and if you need more auto-injectable epinephrine

3. Show the Wallet Card to your doctor or emergency responder when you have any medical treatment for any condition, even if it’s not for your phenylketonuria (PKU). Inform all doctors you are being treated with PALYNZIQ

4. Notify the PALYNZIQ REMS if you change your PALYNZIQ doctors if your contact information changes, or if you discontinue treatment with PALYNZIQ

PALYNZIQ REMS Resources

**Before Prescribing/Dispensing PALYNZIQ**

- Prescribing Information
- REMS Program Overview
- Prescriber Guide
- Prescriber Enrollment Form
- Prescriber Knowledge Assessment

**Before starting PALYNZIQ**

- Patient Guide: What You Need to Know
- Safety Video
- Wallet Card (carry at all times)
- Patient Enrollment Form

PALYNZIQ is indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

Please see the Medication Guide and Prescribing Information, including BOXED WARNING, for more information.
PALYNZIQ REMS Portal Overview

PALYNZIQREMS.com

- PALYNZIQ REMS Portal is a web-based tool designed to:
  - Provide real-time access to PALYNZIQ REMS patient, prescriber, and pharmacy information
  - Maintain compliance with the PALYNZIQ REMS
- PALYNZIQ REMS Portal allows prescribers to instantly certify themselves, enroll patients, and manage their patients online
- PALYNZIQ REMS Portal is accessed with secure username and password provided upon registration

Additional questions:

Please visit PALYNZIQREMS.com or call the PALYNZIQ REMS at 1-855-758-REMS (1-855-758-7367) for more information about the PALYNZIQ REMS.

Please see the Medication Guide and Prescribing Information, including **BOXED WARNING**, for more information.

PALYNZIQREMS.com

Phone: 1-855-758-REMS (1-855-758-7367) Fax: 1-866-713-8421

Mail: PALYNZIQ REMS, 200 Pinecrest Plaza, Morgantown WV 26505