

Welcome to the

## PALYNZIQ REMS (Risk Evaluation and Mitigation Strategy) Program

A 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 outweigh its risks. Due to the risk of anaphylaxis, PALYNZIQ<sup>®</sup> (pegvaliase-pqpz) is only available through a restricted program called the PALYNZIQ REMS.

The goal of the REMS is to mitigate the risk of anaphylaxis associated with PALYNZIQ by:

- Ensuring prescribers are educated on the risk of anaphylaxis associated with the use of PALYNZIQ
- Ensuring that prescribers are educated and adhere to the following:
  - Counsel patients on how to recognize and respond to signs and symptoms of anaphylaxis
  - Enroll patients in the PALYNZIQ REMS
  - Prescribe auto-injectable epinephrine with PALYNZIQ
- Ensuring that PALYNZIQ is only dispensed to patients with documentation of safe use conditions:
  - Patient education and enrollment in the PALYNZIQ REMS
  - Having auto-injectable epinephrine available at all times
- Ensuring that patients are educated on the following:
  - How to recognize and respond to signs and symptoms of anaphylaxis
  - The need to carry auto-injectable epinephrine with them at all times

### PALYNZIQ REMS Overview

- PALYNZIQ is only available through a restricted distribution program called PALYNZIQ REMS
- Prescribers must be certified in the PALYNZIQ REMS and comply with the REMS requirements to prescribe PALYNZIQ
- All PALYNZIQ patients must enroll in the PALYNZIQ REMS to receive PALYNZIQ
- Prescribers must educate and counsel patients on the risks of PALYNZIQ, including the risk of anaphylaxis
- Prescribers must counsel patients on the need to carry auto-injectable epinephrine with them at all times
- Pharmacies must be certified in the PALYNZIQ REMS to dispense PALYNZIQ
- Pharmacies must verify that PALYNZIQ is only dispensed to patients with documentation of safe use conditions

PALYNZIQ is not available to all pharmacies. If you have any questions about the PALYNZIQ REMS or need help enrolling, call 1-855-758-REMS (1-855-758-7367), Monday to Friday, 8:00 am to 8:00 pm (ET).

### Indications

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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Prescribers

### The goal of the PALYNZIQ REMS is to mitigate the risk of anaphylaxis associated with PALYNZIQ by:

- Ensuring prescribers are educated on the risk of anaphylaxis associated with the use of PALYNZIQ
- Ensuring that prescribers are educated and adhere to the following:
  - Counsel patients on how to recognize and respond to signs and symptoms of anaphylaxis
  - Enroll patients in the PALYNZIQ REMS
  - Prescribe auto-injectable epinephrine with PALYNZIQ
- Ensuring that PALYNZIQ is only dispensed to patients with documentation of safe use conditions:
  - Patient education and enrollment in the PALYNZIQ REMS
  - Having auto-injectable epinephrine available at all times
- Ensuring that patients are educated on the following:
  - How to recognize and respond to signs and symptoms of anaphylaxis
  - The need to carry auto-injectable epinephrine with them at all times

Only a limited number of certified pharmacies will dispense PALYNZIQ. Please contact the PALYNZIQ REMS for a list of certified pharmacies.

### To become certified to prescribe PALYNZIQ, prescribers must:

- Read the PALYNZIQ [Prescribing Information \(PI\)](#), [REMS Program Overview](#), and the [Prescriber Guide](#)
- Enroll in the PALYNZIQ REMS by completing and submitting the [Prescriber Knowledge Assessment](#) and the [Prescriber Enrollment Form](#):
  - [Enroll online here](#)
  - **By fax** at 1-866-713-8421
  - **By mail** at PALYNZIQ REMS, 200 Pinecrest Plaza, Morgantown, WV 26505-8065
- Receive an enrollment confirmation from the PALYNZIQ REMS verifying that enrollment has been completed

### Before Treatment Initiation

- Assess the patient's need for an adult observer and for premedication as described in the [Prescriber Guide](#)
- Counsel the patient on the risk of anaphylaxis including how to recognize and respond to anaphylaxis using the [Patient Guide](#), [Safety Video](#), and [Wallet Card](#)
- Provide the patient with the [Patient Guide](#), [Wallet Card](#), and the link to access the [Safety Video](#)
- Enroll the patient in the PALYNZIQ REMS by completing and submitting the [Patient Enrollment Form](#). Provide a completed copy of the form to the patient and retain a completed copy in the patient's record:
  - [Enroll online here](#)
  - **By fax** at 1-866-713-8421
- Provide the patient with a prescription for auto-injectable epinephrine to accompany the prescription for PALYNZIQ
- Educate the patient on when and how to use auto-injectable epinephrine and the need to carry it with them at all times

### During Treatment, Before Each Prescription

- Assess the patient for anaphylaxis episodes
- Assess the patient's supply of auto-injectable epinephrine
- Provide a prescription for auto-injectable epinephrine if the patient's supply is inadequate

### At All Times

- Report anaphylaxis episodes to the PALYNZIQ REMS
- Report treatment discontinuation or transfer of care to the PALYNZIQ REMS

Report anaphylaxis episodes to the PALYNZIQ REMS. Report if an enrolled patient is no longer under your care or has discontinued therapy to the PALYNZIQ REMS at 1-855-758-REMS (1-855-758-7367).

### PDFs for Download

#### Materials for Healthcare Providers

- [Prescriber Guide](#)
- [REMS Program Overview](#)
- [Prescriber Enrollment Form](#)
- [Prescriber Knowledge Assessment](#)



#### Spanish Materials for Healthcare Providers

- [Spanish Prescriber Guide](#)
- [Spanish REMS Program Overview](#)
- [Spanish Prescriber Enrollment Form](#)
- [Spanish Prescriber Knowledge Assessment](#)

#### Materials for Patients

- [Patient Enrollment Form](#)
- [Patient Guide: What You Need to Know](#)
- [Wallet Card](#)
- [Safety Video](#)



#### Spanish Materials for Patients

- [Spanish Patient Enrollment Form](#)
- [Spanish Patient Guide: What You Need to Know](#)
- [Spanish Wallet Card](#)
- [Spanish Safety Video](#)

## Pharmacies

**PALYNZIQ is available only through the PALYNZIQ REMS. Only prescribers, patients, and a limited network of certified pharmacies enrolled are able to prescribe, receive, and dispense PALYNZIQ. If you have questions, please contact the PALYNZIQ REMS at 1-855-758-REMS (1-855-758-7367).**

### To become certified to dispense PALYNZIQ, pharmacies must:

- Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the PALYNZIQ REMS on behalf of the pharmacy
- Have the authorized representative review the **REMS Program Overview**
- Have the authorized representative enroll in the PALYNZIQ REMS by completing and submitting the **Pharmacy Enrollment Form**
- Establish processes and procedures to verify and document the patient has auto-injectable epinephrine and report anaphylaxis episodes to the PALYNZIQ REMS/manufacturer/prescriber
- Train all relevant staff involved in the dispensing of PALYNZIQ on the program requirements using the **REMS Program Overview**

### Before Dispensing:

- Verify and document that the patient has auto-injectable epinephrine through the processes and procedures established as a requirement of the PALYNZIQ REMS
- Obtain authorization to dispense each prescription by contacting the PALYNZIQ REMS to verify prescriber certification and patient enrollment

### To Maintain Certification to Dispense:

- Have the new authorized representative enroll in the PALYNZIQ REMS by completing the **Pharmacy Enrollment Form** if the authorized representative changes

### At All Times:

- Report anaphylaxis episodes to the PALYNZIQ REMS
- Do not distribute, transfer, loan, or sell PALYNZIQ except to certified dispensers
- Maintain records documenting staff's completion of REMS training and that all processes and procedures are in place and are being followed
- Comply with audits carried out by BioMarin or a third party acting on behalf of BioMarin to ensure that all processes and procedures are in place and are being followed

**For information on 340B, contact the PALYNZIQ REMS at 1-855-758-7367.**

### PDFs for Download

#### Materials for Pharmacies

[REMS Program Overview](#)

[Pharmacy Enrollment Form](#)

#### Spanish Materials for Pharmacies

[Spanish REMS Program Overview](#)

[Spanish Pharmacy Enrollment Form](#)



## Patients



**PATIENT SAFETY VIDEO:**  
**Patient must watch the SAFETY VIDEO before enrollment.**

### Requirements for receiving treatment with PALYNZIQ:

- Discuss the following with your doctor and make sure you understand:
  - The risks of PALYNZIQ, including severe allergic reaction (anaphylaxis)
  - The need to carry auto-injectable epinephrine with you at all times and when and how to use it
- Receive and read the **Patient Guide: What You Need To Know** and **Wallet Card** and view the **Safety Video**
  - The **Patient Guide: What You Need To Know** is your comprehensive guide to understanding treatment with PALYNZIQ
  - The **Wallet Card**, which is provided for you to carry during treatment, should be shared with your doctors or emergency responder
  - The **Safety Video** can be viewed to show you how to recognize and respond to signs and symptoms of a severe allergic reaction (anaphylaxis)
- Complete the **Patient Enrollment Form** with your doctor who will provide you with a copy of this form. You can expect to be contacted by the PALYNZIQ REMS
- Fill your prescription for auto-injectable epinephrine before your first dose to ensure that you have it available
  - Inform your doctor if you need more auto-injectable epinephrine if you needed to use it or if it becomes expired

**It is important to tell your doctor if you have a severe allergic reaction (anaphylaxis). Carry the **Wallet Card** and **auto-injectable epinephrine** with you at all times.**

Inform all doctors you are receiving PALYNZIQ.

Contact the PALYNZIQ REMS if you change doctors, if your contact information changes, or if you stop taking PALYNZIQ.

### PDFs for Download

#### Materials for Patients

- [Patient Guide: What You Need to Know](#)
- [Wallet Card](#)
- [Safety Video](#)
- [Medication Guide](#)

#### Spanish Materials for Patients

- [Spanish Patient Guide: What You Need to Know](#)
- [Spanish Wallet Card](#)
- [Spanish Safety Video](#)
- [Spanish Medication Guide](#)



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## Contact Us

### Phone

**1-855-758-REMS**  
**(1-855-758-7367)**

### Fax

**1-866-713-8421**

### Hours of Operation

**Monday - Friday**  
**8:00 AM-8:00 PM**  
**Eastern**



To learn more about the serious risks associated with PALYNZIQ, please refer to the [Prescribing Information](#) including [Boxed Warning](#), [Medication Guide](#), [Prescriber Guide](#), [Patient Guide: What You Need to Know](#), and [REMS Program Overview](#).

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## Login

### Login

Your username was supplied to you via email when you registered. If you need assistance, please call 1-855-758-REMS (1-855-758-7367).

Please enter your username

[LOGIN](#)

OR

### Do not have an online account?

### Prescriber Registration

To create your prescriber web account for the PALYNZIQ REMS, please complete the fields below.

\* NPI

[CONTINUE](#)

\*Note online registration is for prescribers only. Pharmacy users must submit enrollment via fax and will receive username via email.

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