PALYNZIQ
REMS Patient Guide

What You Need to Know

Enroll

Before starting PALYNZIQ® (pegvaliase-pqpz)

1 **Discuss** with your healthcare provider and understand:
- The risks associated with PALYNZIQ, including a severe allergic reaction (anaphylaxis)
- The need for 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

During Treatment

After starting PALYNZIQ

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

2 **Inform** your doctor 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 healthcare providers you are being treated with PALYNZIQ

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

Patients: Your doctor will go over this **Patient Guide** and **Safety Video** with you. It is important to ask any questions you may have at any time while receiving PALYNZIQ. Keep this guide for Important Safety Information about the serious risks of PALYNZIQ.

Prescribers: Review this **Patient Guide** and **Safety Video** with your patient and provide your patient a copy to take home.

Palynziq®
(pegvaliase-pqpz) Injection

Reference ID: 4681560

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What is PALYNZIQ?

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.

What is the Most Serious Risk of PALYNZIQ?

PALYNZIQ can cause a severe allergic reaction (anaphylaxis) that may be life-threatening and can happen anytime during treatment with PALYNZIQ. You will receive your first injection of PALYNZIQ in a healthcare setting where you will be closely watched for at least 1 hour after your injection for a severe allergic reaction.

Stop injecting PALYNZIQ and call 911 or go to the closest emergency medical center if you have any of the following symptoms of a severe allergic reaction during treatment with PALYNZIQ:

- fainting (passing out)
- dizziness or lightheadedness
- sudden confusion
- trouble breathing or wheezing
- chest discomfort or chest tightness
- fast heart rate
- swelling of your face, lips, eyes, or tongue
- throat tightness
- flushed skin
- skin rash, itching, or raised bumps on skin
- nausea, vomiting, or diarrhea
- losing control of urine or stools

Your healthcare provider will prescribe auto-injectable epinephrine and will teach you (or your caregiver) and your observer (if needed) when and how to use it if you should have a severe allergic reaction. **Keep the auto-injectable epinephrine with you at all times.** Read the Patient Information that comes with the auto-injectable epinephrine that your healthcare provider prescribes for you for more information.

Your healthcare provider may recommend that an adult observer (or your caregiver) be with you when you give your PALYNZIQ injection, and for at least 1 hour after your injection to watch you for signs and symptoms of a severe allergic reaction and, if needed, give you an injection of epinephrine and call for emergency medical help.

If you have a severe allergic reaction, do not continue to take PALYNZIQ until you talk with your healthcare provider. Tell your healthcare provider that you had a severe allergic reaction. Your healthcare provider will tell you if you can continue treatment with PALYNZIQ. Your healthcare provider may prescribe other medicine to take before your PALYNZIQ injection that help reduce the symptoms of an allergic reaction. If your healthcare provider decides that you can continue treatment with PALYNZIQ after a severe allergic reaction, you will receive your next injection of PALYNZIQ in a healthcare setting where you will be closely watched for at least 1 hour after your injection for a severe allergic reaction.

What is the PALYNZIQ REMS?

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.

Because of the risk of a severe allergic reaction (anaphylaxis), PALYNZIQ is only available through a restricted program called the PALYNZIQ REMS.

The PALYNZIQ REMS educates patients and doctors about the risk associated with PALYNZIQ.

Requirements of the PALYNZIQ REMS include the following:

- Understand the risk of a severe allergic reaction (anaphylaxis) associated with PALYNZIQ
- You and your doctor must be enrolled in the PALYNZIQ REMS in order to receive and prescribe PALYNZIQ
- You must fill a prescription for auto-injectable epinephrine and carry auto-injectable epinephrine with you **at all times**
- PALYNZIQ is only available from pharmacies that participate in the PALYNZIQ REMS

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How Do I Enroll in the PALYNZIQ REMS, and What is Required of Me?

1. **Discuss** with your doctor and understand:
   - The risk of a severe allergic reaction (anaphylaxis)
   - The need to carry auto-injectable epinephrine with you **at all times**
2. **Receive** and **read**:
   - This *Patient Guide*
   - The *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 before your first dose of PALYNZIQ to ensure you have it available

After Enrolling, What Are the Next Steps? How Will I Receive PALYNZIQ?

Upon enrollment:

- A representative from the PALYNZIQ REMS will contact you to get you started
- The pharmacy will call you to schedule a shipment of PALYNZIQ that will come right to your home
  - PALYNZIQ is only available from pharmacies that participate in the PALYNZIQ REMS
  - The pharmacy will verify that you have received and filled a prescription for auto-injectable epinephrine and that you and your doctor are enrolled in the PALYNZIQ REMS

After starting PALYNZIQ:

- Carry auto-injectable epinephrine with you at all times
- Inform your doctor if you have any signs or symptoms of a severe allergic reaction (anaphylaxis) after receiving PALYNZIQ and if you need more auto-injectable epinephrine (if you needed to use it or if it expired)
- Show the *Wallet Card* to your doctor or emergency responder when you have any medical treatment, even if it is not for your PKU
- Notify the PALYNZIQ REMS if you change your PALYNZIQ doctor, if your contact information changes, or if you discontinue treatment with PALYNZIQ

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Additional Questions:

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

Fax: 1-866-713-8421

Mail: PALYNZIQ REMS, 200 Pinecrest Plaza, Morgantown, WV 26505-8065

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