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.
What is the PALYNZIQ REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential 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 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 time of PALYNZIQ initiation or dose escalation. Anaphylaxis is a severe and lifethreatening reaction; if you experience any signs or symptoms of anaphylaxis, call 1-855-758-REMS (1-855-758-7367), seek immediate medical attention, and do not receive another dose of PALYNZIQ.
- Anaphylaxis has been reported in patients who have used PALYNZIQ. PALYNZIQ may cause anaphylaxis (serious and life-threatening allergic reactions) that may be either immediate or delayed. Immediate anaphylaxis is a severe and potentially life-threatening medical emergency. The signs and symptoms of anaphylaxis may include:
  - Anaphylaxis episodes can occur quickly. Immediately inform your prescriber of any signs and symptoms, the appropriate care, and when to seek immediate medical care.

What are the Requirements of the PALYNZIQ REMS?

- Become certified by completing a one-time certification process.
  - 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 by:
    - Training staff and review REMS resources with the patient.
    - Review the Patient Enrollment Form with your patient.
    - Ask prescriber to provide an auto-injectable epinephrine and carry it with the patient.

How Does the PALYNZIQ REMS Work?

- Counsel and enroll patient and prescribe auto-injectable epinephrine.
  - Before dispensing, verify prescriber certification, enroll patient in the PALYNZIQ REMS, and complete the Prescription Enrollment Form. Before dispensing, verify prescriber certification, enroll patient in the PALYNZIQ REMS, and complete the Prescription Enrollment Form.
  - Before starting each dose, verify the patient has an auto-injectable epinephrine and carry it with the patient.

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  - 1. Become certified by completing a one-time certification process.
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    - Training staff and review REMS resources with the patient.
    - Review the Patient Enrollment Form with your patient.
    - Ask prescriber to provide an auto-injectable epinephrine and carry it with the patient.

Pharmacy Requirements

- To dispense PALYNZIQ:
  - 1. Designate an authorized representative for the pharmacy. He or she will need to receive the REMS Program Overview and will oversee implementation and ensure compliance with the PALYNZIQ REMS requirements.
  - 2. Once the step is completed, the PALYNZIQ REMS will contact the pharmacy to complete the Patient Enrollment Form. Make sure your pharmacy’s name and address are correct in the form.
  - 3. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.
  - 4. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.
  - 5. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.
  - 6. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.

Ensure Compliance with REMS Requirements

- Before dispensing PALYNZIQ:
  - 1. Designate an authorized representative for the pharmacy. He or she will need to receive the REMS Program Overview and will oversee implementation and ensure compliance with the PALYNZIQ REMS requirements.
  - 2. Once the step is completed, the PALYNZIQ REMS will contact the pharmacy to complete the Patient Enrollment Form. Make sure your pharmacy’s name and address are correct in the form.
  - 3. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.
  - 4. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.
  - 5. You must verify the patient’s need for an auto-injectable epinephrine and the patient is authorized to receive PALYNZIQ and has an auto-injectable epinephrine.