

# Pegvaliase (PALYNZIQ®▼)

## Patient alert card

---

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get directly to BioMarin via [drugsafety@bmrn.com](mailto:drugsafety@bmrn.com); Fax: +1-415-532-3144 or Tel: +1-415-506-6179. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>, and sent by post or email to: P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Ġwann SGN 3000 E: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

Patient name: \_\_\_\_\_

Age: \_\_\_\_\_

Allergy information: \_\_\_\_\_

Other health issues (such as asthma): \_\_\_\_\_

**Emergency contact details:**

Emergency contact name: \_\_\_\_\_

Emergency contact information: \_\_\_\_\_

Doctor's name: \_\_\_\_\_

Doctor's contact information: \_\_\_\_\_

Doctor's contact information after hours: \_\_\_\_\_

**Pegvaliase can cause severe allergic reactions that may be life threatening** and these can happen any time after a pegvaliase injection. **Stop injecting pegvaliase if any of the following symptoms occur**

**IMPORTANT: Carry an adrenaline injection device and this card with you at all times. Show card to medical personnel in the event of an emergency.**

**Symptoms of severe allergic reactions can include:**

- Swelling of the face, eyes, lips, mouth, throat, tongue, hands and/or feet
- Trouble breathing or wheezing
- Throat tightness or choking feeling
- Trouble swallowing or speaking
- Feeling dizzy or fainting
- Losing control of urine or stools
- Rapid heartbeat
- Hives (like an itchy, bumpy skin rash) that spreads quickly
- Flushing
- Severe stomach cramps or pain, vomiting, or diarrhoea

### What to do if you experience a severe allergic reaction:

- Stop injecting pegvaliase
- Take adrenaline if needed (prior to starting pegvaliase, your doctor will prescribe an adrenaline injection device and train you and your observer on when and how to use adrenaline). Keep the adrenaline injection device with you at all times
- Call for urgent medical assistance or go to the closest emergency medical centre

### FOR HEALTHCARE PROFESSIONALS

This patient has been prescribed pegvaliase. Severe allergic reactions have been associated with the use of this product.

For more information about pegvaliase, please refer to the Summary of Product Characteristics.

Please report any suspected adverse reactions to [drugsafety@bmrn.com](mailto:drugsafety@bmrn.com) via national reporting systems.