

Important information for patients and trained observers for the safe use of pegvaliase▼ (PALYNZIQ®)

▼ 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; 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 Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 E: postlicensing.medicinesauthority@gov.mt

Pegvaliase can cause severe allergic reactions which may require immediate treatment. This leaflet contains important information on how to prevent these reactions and what to do if they occur. Please read this carefully and keep it in a safe and easily accessible place.

Severe allergic reactions

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:

- 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

- **Use adrenaline injection device as instructed by your doctor and seek urgent medical assistance**

Your doctor will prescribe an adrenaline injection device to use for a severe allergic reaction. Your doctor will train and instruct you and someone helping you on when and how to use adrenaline. Keep the adrenaline injection device with you at all times.

Prevention of severe allergic reactions

1. Starting pegvaliase (for patients)

- Your healthcare provider will give you the pegvaliase injection until you (or a caregiver) can do it yourself
- Your doctor will prescribe medicines for you to take before your pegvaliase injection, such as paracetamol, fexofenadine, and/or ranitidine. These medicines help to reduce the symptoms of an allergic reaction
- A healthcare provider will monitor you for at least 1 hour after you get pegvaliase for signs and symptoms of an allergic reaction
- Your doctor will also prescribe an adrenaline injection device for use for any severe allergic reactions. Your healthcare provider will also tell you which signs and symptoms to look out for and what to do if you get a severe allergic reaction
- Your doctor will show you how and when to use the adrenaline injection device. Keep it with you at all times
- If adrenaline is needed, you should seek immediate medical care following its use

2. Continuing pegvaliase (for patients)

- Your doctor will tell you how long to continue taking medicines such as paracetamol, fexofenadine and/or ranitidine before you take pegvaliase
- You must have someone with you when you inject pegvaliase and for at least 1 hour after your injection to watch for signs and symptoms of a severe allergic reaction and, if needed, give you an injection of adrenaline and call for emergency medical help
- Your doctor will train them on the signs and symptoms of a severe allergic reaction and how to give an injection of adrenaline
- Your doctor will tell you if you need an observer for longer than 6 months

3. Responsibilities as a pegvaliase Trained Observer (for Trained Observers)

- The doctor will train you on:
 - a. How to recognise signs and symptoms of an acute systemic hypersensitivity reaction
 - b. The need to seek immediate medical care if a reaction occurs
 - c. How to properly administer adrenaline injection device (auto-injector or pre-filled syringe/pen)
- You must be present during and for at least 60 minutes after pegvaliase injection
- You must observe the patient for signs and symptoms of an acute systemic hypersensitivity reaction
- If you identify an acute systemic hypersensitivity reaction in the patient, you must administer adrenaline injection device as needed, and call for urgent medical assistance or take the patient to the closest emergency medical centre

Patients, if you have had a severe allergic reaction, do not continue to use pegvaliase until you talk with the doctor who prescribes you pegvaliase. Tell your doctor you had an allergic reaction. Your doctor will tell you if you can continue pegvaliase treatment.

A patient alert card with emergency information has also been provided for you to keep in your wallet. Please carry this card with you at all times.

Please also carefully read the package leaflet contained in each pack/carton of pegvaliase.