

## Risk Mitigation Material

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

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) or BioMarin Pharmaceutical Inc. at 1-866-906-6100. Reporting of side effects is possible also via national reporting systems. Reporting forms and information can be found at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>

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.

<b>Severe allergic reactions</b>
<b>Pegvaliase can cause severe allergic reactions that may be life threatening;</b> these reactions can happen immediately after injection, most commonly occur within 60 minutes of injection, and rarely can occur up to 24 hours after injection. Severe allergic reactions can occur at any time throughout treatment with pegvaliase
<b>Stop injecting pegvaliase if any of the following symptoms occur:</b> <ul style="list-style-type: none"><li>•Swelling of the face, eyes, lips, mouth, throat, tongue, hands and/or feet</li><li>•Hives (like an itchy, bumpy skin rash) that spreads quickly</li><li>•Flushing</li><li>•Trouble breathing or wheezing</li><li>•Throat tightness or choking feeling</li><li>•Trouble swallowing or speaking</li><li>•Feeling dizzy or fainting</li><li>•Losing control of urine or stools</li><li>•Rapid heartbeat</li><li>•Severe stomach cramps or pain, vomiting, or diarrhea</li></ul>
<b>What to do if you experience a severe allergic reaction</b> <ul style="list-style-type: none"><li>•Use epinephrine injection device as instructed by your doctor and seek urgent medical assistance</li></ul>
Your doctor will prescribe an epinephrine 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 epinephrine. Keep the epinephrine injection device with you at all times.

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## **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 acetaminophen, 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 epinephrine 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 epinephrine injection device. Keep it with you at all times
- If epinephrine 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 acetaminophen, fexofenadine and/or ranitidine before you take pegvaliase
- For at least the first 6 months of PALYNZIQ® treatment, you must have someone with you when you self-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 epinephrine 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 epinephrine
- 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 a severe allergic reaction
  - b.The need to seek immediate medical care if a reaction occurs
  - c.How to properly administer epinephrine injection device
- You must be present during and for at least 60 minutes after pegvaliase injection
- You must observe the patient for signs and symptoms of a severe allergic reaction

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- If you identify a severe allergic reaction in the patient, you must administer epinephrine injection device as needed, and call for emergency medical help

**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 Patient Medication Information contained in each pack/carton of pegvaliase.

**Palynziq 2.5 mg/0.5 mL DIN: 02526247**

**Palynziq 10 mg/0.5 mL DIN: 02526255**

**Palynziq 20 mg/1.0 mL DIN 02526263**

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