

# LOARGYS▼ (PEGZILARGINASE) - IMPORTANT INFORMATION ON MINIMISING THE RISK OF HYPERSENSITIVITY REACTIONS AND MEDICATION ERRORS FOLLOWING SELF ADMINISTRATION AT HOME

▼ *This medicine 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.*

This guidance is intended as a supporting document to the instructions and training provided by your healthcare personnel. Contact your healthcare professional if you have any question.

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## Introduction

Together with your doctor, it has been decided that you or a caregiver will carry out the injection of Loargys (pegzilarginase) yourselves at home. This guide supplements the information in the package leaflet and the information provided by your treating doctor. This guide aims to inform you about:

- the importance of proper handling
- preparation and administration of pegzilarginase to reduce the risk of medication errors
- the risk of Allergic (hypersensitivity) reactions
- how to report side effects

A tracker is provided in the form of a table to help you record injections and associated injection site to help you rotate injection sites.

Please talk to your doctor or nurse if you have any further questions about use.

## Allergic reactions

Pegzilarginase may cause Allergic (hypersensitivity) reactions. Symptoms may include swelling of your face, skin rash and sudden redness of the skin (flushing). This is most likely to occur after the first few doses. Your doctor might prescribe medicines to prevent hypersensitivity reactions, which you must take before you are injected with pegzilarginase.

Severe allergic reactions may be life-threatening if not treated immediately. You and/or your caregiver must therefore pay attention to the following signs and symptoms of a severe allergic reaction including:

- hives
- generalised itching
- tightness of the chest
- difficulty breathing
- low blood pressure

If a symptom of a severe allergic reaction occurs, immediately stop administration of pegzilarginase and contact your healthcare professional or emergency department.

## Reporting of side effects

Please report suspected side effects to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- the free Yellow Card app available from the Apple App Store or Google Play Store

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting, please provide as much information as possible including the brand name and batch number. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to Immedica Pharma at [safety@immedica.com](mailto:safety@immedica.com)

## Preparing a dose of pegzilarginase

The steps below describe how to prepare and give pegzilarginase at home, as an injection under the skin. Before injecting this medicine, you should first have received training from your doctor or nurse on how to prepare and inject pegzilarginase. Do not inject this medicine unless you have received training, and you understand the steps.

Your doctor will prescribe your correct dose and will tell you what volume (in ml) to inject. You may need more than one pegzilarginase vial to get the correct dose and you may need to divide the total dose into more than one injection. Your doctor or nurse will tell you exactly how to give the correct dose.

Each vial is for single use only, always use new vial(s) for each dose. Pegzilarginase should not be mixed with other solutions for injection. Do not shake the medication.

Your healthcare provider will provide you with the necessary supplies to perform the injection. The vials must be stored in a refrigerator at a temperature between +2 °C and +8 °C.

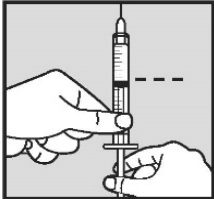
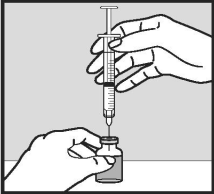

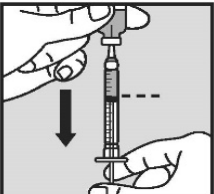
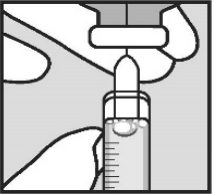
Make sure you have everything you need for the injection(s):

- Pegzilarginase vial(s)
- A graduated syringe
- 1 large needle (e.g. 18 Gauge) per vial, to withdraw the dose
- 1 small needle (e.g. 26 -27 Gauge) per injection
- Alcohol wipes
- Gauze pad
- Plaster, if required
- Sharps container

### Important checks to make

- Check the name and the strength of the vial(s) to make sure it contains the correct medicine and that you have the correct number of vials at hand. Check the expiry date on the carton. Do not use if the product has expired.
- Take the unopened pegzilarginase vial(s) out of the refrigerator **15 to 30 minutes** before the planned injection to allow the solution to reach room temperature. Do not use external heat.
- Wash your hands.
- The solution in the vial should be colourless to slightly yellow or slightly pink, clear to slightly opalescent (pearly). Do not use if the solution is cloudy or contains visible particles.
- Place the vial on a clean flat surface. Remove the plastic flip-off cap from the vial.
- Wipe the top of the vial with an alcohol swab and allow to air dry. Do not touch the top of the vial or allow it to touch anything else once wiped.

## Withdrawing solution from the vial:

<p>1. Attach a large needle to the graduated syringe. Remove the needle cap.</p>	
<p>2. Pull the plunger back to draw air into the graduated syringe, equal to the volume to withdraw from the vial (in ml).</p>	
<p>3. Keep the vial on a flat surface, slowly insert the needle through the rubber seal into the vial.</p> <p>a) <b>For single or first vial:</b> The tip of the needle should not touch the solution to avoid forming foam. Continue to step 4.</p> <p>b) <b>For subsequent vial(s):</b> Turn the vial upside down, ensure the needle tip is in the air space above the solution to avoid forming foam.</p>	 
<p>4. Slowly push the plunger to inject the air into the vial.</p>	
<p>5. Keep the needle in the vial and hold it upside down. With the needle in the solution, slowly pull the plunger to the mark equal to the volume needed.</p>	
<p>6. Before removing the needle from the vial, check the solution in the syringe for air bubbles. If there are bubbles, continue to hold the vial upside down with the needle pointing upwards. Gently tap the barrel of the syringe with your finger. Once all the air bubbles are at the top, gently push the plunger to push out the bubbles through the needle.</p>	
<p>7. Check the volume to give (in ml), against the markings on the syringe to make sure that you have withdrawn the correct amount of solution.</p>	
<p>8. Pull the needle from the vial, put the needle cap back on and dispose it in your sharps container.</p>	
<p>9. You may need to use several vials to withdraw the complete volume (in ml). To do this, repeat steps 1-8 above for each vial needed to obtain the total dose (in ml) or as shown to you by your doctor or nurse. Always follow the instructions given to you by your doctor or nurse. Please note that for each new vial you should also use a new needle.</p>	
<p>10. Place a small needle on the filled syringe, do not remove the needle cap. Ensure the needle sits tight.  <u>Note:</u> If the solution is not to be used immediately, take note of the storage conditions.</p>	

## Storage

The dose should be given as soon as possible after drawn up into the syringe, but once the dose has been drawn up in the syringe it can be stored for:

- 2 hours when stored at room temperature up to 25 °C, or
- up to 4 hours if stored refrigerated at 2 °C to 8 °C before giving the dose. After this time, the prepared Pegzilarginase cannot be used anymore and must be discarded.

## Administering the dose:

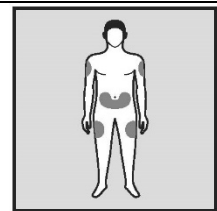
1. Remove the needle cap. Hold the syringe with the needle pointing up and tap the barrel of the syringe with your finger to remove any air bubbles.

Control visually that the volume contained in the syringe is correct. The volume per injection should not exceed 1 ml. If it is the case, multiple injections should be injected at different sites.

2. Choose an injection site (abdomen, side of the thigh, or the side or back of the upper arms). Rotate injection sites between doses.

Do not inject into scar tissue or areas that are reddened, inflamed, or swollen. If injecting into the abdomen, avoid the area directly surrounding the navel.

If more than 1 injection is needed for a single dose of pegzilarginase, the injection sites should be at least 3 cm apart.

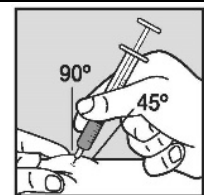


3. Clean the injection site using an alcohol swab and allow the skin to dry.

4. Gently pinch the skin of the chosen injection site between your thumb and index finger.

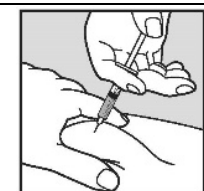


5. Hold the syringe like a pencil or dart. Insert the needle into the raised skin at a 45° to 90° angle.



6. While continuing to pinch the skin, slowly push the plunger until you have injected the desired volume.

**Reminder:** If you need to inject a volume of more than 1 ml of pegzilarginase, switch the injection site and make sure that the new injection site is more than 3 cm away. Slowly press the plunger down until you have injected the volume needed. Repeat until you have injected your total dose (in ml). Always use a new small needle for each injection.



7. Remove the syringe by pulling it straight out. Release the pinched skin and gently press a gauze pad over the injection site for a few seconds. Apply a plaster or cotton wool and tape if needed.

8. Put the used syringe, needles and caps in the sharps container. Used vials, even if not empty, should be discarded according to your local guidelines.

## Record keeping

Note the date of the injection and all the sites where you have injected. This helps you to use a different injection site for the next injection.

Date of use	Injection site	Batch number

## Further information

For further copies of this guide, please contact Immedica at [info-uk@immedica.com](mailto:info-uk@immedica.com)

If you have any questions about your treatment please contact your doctor.

The patient information leaflet is available on the link below:

<https://www.medicines.org.uk/emc/files/pil.15382.pdf>

