Combi art. 4141

pegzilarginase
ENE

Package leaflet / Gebrauchsinformation
Information for the patient / Information für Patienten
Loargys 5 mg/ml solution for injection/infusion/
Injektions-/Infusionslösung
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EN **Package leaflet: Information for the patient**

Loargys 5 mg/ml solution for injection/infusion

pegzilarginase

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Loargys is and what it is used for

Loargys contains the active substance pegzilarginase, which is a modified human enzyme produced by recombinant DNA technology. The medicine is used to treat arginase 1 deficiency (ARG1-D), also known as hyperargininemia, in adults, adolescents and children aged 2 years and older.

Patients with ARG1-D have low levels of an enzyme called arginase. This enzyme helps the body control levels of arginine, an amino acid needed by your body to make proteins. If arginine is not controlled it can build up in the body and cause symptoms, like problems with muscle control.

Loargys is used in combination with other ways to manage the disease. These may include:
- a diet that is low in protein
- food supplements with essential amino acids
- medicines to manage other symptoms of the disease, such as medicines that lower levels of ammonia in your body.

How Loargys works

Pegzilarginase, the active substance in Loargys, acts similarly to the natural enzyme arginase, which is lacking or not working properly in patients with ARG1-D. This lowers arginine levels in the blood, thereby reducing the disease symptoms.

2. What you need to know before you are given Loargys

You must not be given Loargys
- if you have had a severe allergic reaction to pegzilarginase or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Loargys may cause allergic reactions. This is most likely to occur after the first few doses.
Stop the injection immediately and contact your health care provider or emergency department if you experience any of the following symptoms of a severe allergic reaction: hives, generalised itching, tightness of the chest, difficulty breathing or low blood pressure. Your doctor may decide you need additional medical treatment to either prevent or treat an allergic reaction.

During your treatment, your doctor will do blood tests to check what dose of Loargys is right for you.

Children and adolescents

The medicine should not be used in children under 2 years of age, because it is not known if Loargys is safe and effective in this age group.

Other medicines and Loargys

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Loargys is not recommended for use if you are pregnant.

It is not known if the medicine passes into breast milk. If you are breast-feeding, ask your doctor for advice before taking this medicine. Your doctor will help you decide whether to stop breast-feeding or to stop treatment.

Driving and using machines

Loargys has no or negligible influence on the ability to drive and use machines.

Loargys contains sodium and potassium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3. How Loargys is given

Loargys will be given to you by a healthcare professional.
Your doctor will decide the amount of Loargys given to you.

The recommended starting dose of Loargys is 0.1 mg per kilogram of your body weight taken once per week. The dose may be increased or decreased by your doctor to keep your blood arginine levels under control. Your doctor will do regular blood tests to check your blood arginine levels and change your dose if needed.

Loargys is given as an infusion (drip) directly into your vein or as an injection under the skin, as considered appropriate by your doctor.

Your doctor may decide you can be given Loargys at home, as an injection under the skin. After being trained by the doctor or nurse, you can inject Loargys yourself, see instructions in section 7 below.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

If you are given more Loargys than you should

Your doctor will ensure that you receive the right amount of Loargys. If you have been given too much Loargys, your blood arginine level may become too low. Symptoms may include nausea, vomiting, diarrhoea and tiredness. If you or your doctor suspects that you have been given more Loargys than you should, you should be closely monitored and given treatment as needed.

If you forget to use Loargys

If you have missed a dose of Loargys, contact your doctor to schedule the next dose as soon as possible. You should not be given a double dose to make up for a forgotten dose and there should be at least 4 days between doses.

If you stop using Loargys

Your doctor will decide if you should stop using Loargys. If you stop using Loargys, your blood arginine level is likely to increase again.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)
- Allergic reaction (hypersensitivity). Symptoms may include swelling of your face, skin rash and sudden redness of the skin (flushing).

Common (may affect up to 1 in 10 people)
- Injection site reaction. Symptoms may include swelling, redness and rash around the site of injection.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Loargys

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original carton in order to protect from light.

Once removed from the refrigerator, Loargys can be stored for 2 hours at room temperature up to 25 °C.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Loargys contains
- The active substance is pegzilarginase.
- Each 0.4 ml vial contains 2 mg pegzilarginase.
- Each 1 ml vial contains 5 mg pegzilarginase.
- The other ingredients are sodium chloride, potassium dihydrogen phosphate, dipotassium phosphate, glycerol, hydrochloric acid, sodium hydroxide and water for injections. Loargys contains sodium and potassium, see section 2.

What Loargys looks like and contents of the pack

Loargys is a colourless to slightly yellow or slightly pink, clear to slightly opalescent (pearly) liquid, in a clear glass vial.

Each pack contains 1 vial with either 0.4 ml or 1 ml solution for injection/infusion.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Immedica Pharma AB
113 63 Stockholm
Sweden

This leaflet was last revised in 12/2023.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. There are also links to other websites about rare diseases and treatments.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

7. Instructions for use

The steps below describe how to prepare and give Loargys at home, as an injection under the skin. If you are injecting this medicine yourself, you will be trained how to prepare and inject Loargys by your doctor or nurse.

Do not inject this medicine yourself 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 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 what is right for you.

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

Preparation:

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

1. Check the name and the strength of the package to make sure it contains the correct medicine. Check the expiry date on the carton. Do not use if the product has expired.
2. Take the unopened Loargys 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.
3. Wash your hands.
4. 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.
5. Place the vial on a clean flat surface. Remove the plastic flip-off cap from the vial.
6. 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:

1. Attach a large needle to the empty graduated syringe. Remove the needle cap.
2. Pull the plunger back to draw air into the graduated syringe, equal to your dose (in ml).

3. Keep the vial on a flat surface, slowly insert the needle through the rubber seal into the vial. Avoid having the tip of the needle touching the solution.

4. Slowly push the plunger in completely to inject the air into the vial.
5. Keep the needle in the vial and turn it upside down. With the needle in the solution, slowly pull the plunger to the mark equal to your dose.

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.

7. Check your dose again (in ml) against the markings on the syringe. Repeat the process if required. You may need to use several vials to withdraw the complete volume.
8. Pull the syringe and needle from the vial and put the needle cap back on.
9. Remove the needle from the syringe and dispose it in your sharps container.

Giving the dose:

1. Place a small needle on the filled syringe, do not remove the needle cap. Ensure the needle sits tight.

   Note: If the solution is not to be used immediately, the syringe cap should be carefully put back on the syringe tip. Do not touch the syringe tip or the inside of the cap. Protect the syringe from light.

   After preparation, Loargys can be stored at room temperature (up to 25 °C) for up to 2 hours before administration. After this time, the prepared Loargys cannot be used anymore and must be discarded.
2. 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.
3. 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 Loargys, the injection sites should be at least 3 cm apart.
4. Clean the injection site using an alcohol swab and allow the skin to dry.
5. Gently pinch the skin of the chosen injection site between your thumb and index finger.

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

   

7. While continuing to pinch the skin, slowly push the plunger until the syringe is empty.

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

Reminder: If you need more than one injection for your total prescribed dose, the injection sites should be at least 3 cm apart, repeat the procedure above as needed. Always use a new small needle for each injection.

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.

The following information is intended for healthcare professionals only:

Loargys is intended for intravenous infusion or subcutaneous injection.
Use aseptic technique when preparing and administering Loargys.
Do not shake.

Instruction for preparation
- Determine the total volume of Loargys to be administered (and the number of vials needed) based on the patient's weight and dose level.
- Remove the vial(s) from the refrigerator to reach room temperature.
- Inspect the vial visually for particulate matter and discoloration prior to administration.
  - o Loargys is a colourless to slightly yellow or slightly pink, clear to slightly opalescent liquid, essentially free of visible foreign particles.
  - o Discard any vial(s) not consistent with this appearance.
- Withdraw the intended dose into the syringe.
- Chemical and physical stability for the prepared dose has been demonstrated 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. If the product is not used within these time frames, it must be discarded. From a microbiological point of view, the product should be used immediately after reconstitution.

For intravenous administration
- Dilute with sodium chloride 9 mg/ml (0.9 %) solution for injection to achieve the desired volume of infusion (maximum pegzilarginase concentration 0.5 mg/ml).
- Administer the intravenous infusion over at least 30 minutes.
- Do not mix other medicines with Loargys or infuse other medicines concomitantly via the same intravenous access line.

For subcutaneous administration
- Administer the undiluted solution as subcutaneous injection into the abdomen, lateral part 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 Loargys, the injection sites should be at least 3 cm apart.

Discard unused portion of the medicine.

No special requirements for disposal.

BG: Тази листовка е налична на всички езици на ЕС/ЕИП на уебсайта на Европейската агенция по лекарствата.

CS: Na webových stránkách Evropské agentury pro léčivé přípravky je tato příbalová informace k dispozici ve všech úředních jazycích EU/EHP.

DA: Denne indlægsseddel findes på alle EU-/EØS-sprog på Det Europæiske Lægemiddelagenturs hjemmeside http://www.ema.europa.eu.

ET: See infoleht on kõigis EL/EMPi keeltes Euroopa Ravimiameti kodulehel.

FI: Tämä pakkausseloste on saatavissa kaikilla EU-kielillä Euroopan lääkeviraston verkkosivustolla.

EL: Το παρόν φύλλο οδηγιών χρήσης είναι διαθέσιμο σε όλες τις επίσημες γλώσσες της ΕΕ/ΕΟΧ στον δικτυακό τόπο του Ευρωπαϊκού Οργανισμού Φαρμάκων.

HR: Ova uputa o lijeku dostupna je na svim jezicima EU-a/EGP-a na internetskim stranicama Europske agencije za lijekove.

HU: A betegtájékoztató az EU/EGT összes hivatalos nyelvén elérhető az Európai Gyógyszerügynökség internetes honlapján.

IS: Þessi fylgiseðill er birtur á vef Lyfjastofnunar Evrópu á tungumálum allra ríkja Evrópska efnahagssvæðisins.

IT: Questo foglio è disponibile in tutte le lingue dell'Unione europea/dello Spazio economico europeo sul sito web dell'Agenzia europea per i medicinali.

LT: Šis lapelis pateikiamas Europos vaistų agentūros tinklalapyje visomis ES/EEE kalbomis.

LV: Šī lietošanas instrukcija ir pieejama visās ES/EEZ valodās Eiropas Zāļu aģentūras tīmekļa vietnē.

NO: Dette pakningsvedlegget er tilgjengelig på alle EU/EØS-språk på nettstedet til Det europeiske legemiddelkontoret (the European Medicines Agency).

PL: Ta ulotka jest dostępna we wszystkich językach UE/EOG na stronie internetowej Europejskiej Agencji Leków.

PT: Este folheto está disponível em todas as línguas da UE/EEE no sítio da internet da Agência Europeia de Medicamentos.

RO: Acest prospect este disponibil în toate limbile UE/SEE pe site-ul Agenției Europene pentru Medicamente.

SV: Denna bipacksedel finns på samtliga EU-/EES-språk på Europeiska läkemedelsmyndighetens webbplats.

SL: To navodilo za uporabo je na voljo v vseh uradnih jezikih EU/EGP na spletni strani Evropske agencije za zdravila.

SK: Táto písomná informácia je dostupná vo všetkých jazykoch EÚ/EHP na webovej stránke Európskej agentúry pre lieky.

EN: This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

You can find the information also when scanning the QR code below with a smartphone or via the website http://www.loargyspatient.eu

Immedica pharma

Product name: Loargys

Strength: 5 mg/ml

Formulation: solution for injection/infusion

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Languages: en, de

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