Package leaflet: Information for the patient

LysaKare® 25 g/25 g solution for infusion
L-arginine hydrochloride/L-lysine hydrochloride

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LysaKare is and what it is used for

What LysaKare is
LysaKare contains the active substances arginine and lysine, two different amino acids. It belongs to a group of medicines which are used to reduce the side effects of anti-cancer medicine.

What LysaKare is used for
LysaKare is used in adult patients to protect kidneys from unnecessary radiation during treatment with Lutathera (lutetium (^{177}Lu) oxodotreotide), a radioactive medicine used to treat certain tumours.

2. What you need to know before you take LysaKare

Follow all of your doctor's instructions carefully. As you will receive another treatment, Lutathera, with LysaKare, **read the Lutathera leaflet carefully as well as this leaflet.**
If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

You should not be given LysaKare
- if you are allergic to arginine and lysine or any of the other ingredients of this medicine (listed in section 6).
- If you have high blood levels of potassium (hyperkalaemia).

Warnings and precautions
Talk to your doctor before taking LysaKare if your kidneys, heart or liver are severely impaired or if you have a history of high blood levels of potassium (hyperkalaemia).
Because feeling sick (nausea) and vomiting are commonly seen with amino acid infusions, you will be given medicines to prevent nausea and vomiting 30 minutes before the LysaKare infusion.

The doctor will check your blood potassium levels, and will correct them if they are too high before starting the infusion. The doctor will also check your kidney and liver function before starting the infusion. For other tests which need to be performed before your treatment, please read the Lutathera leaflet.
Follow your doctor's advice on how much fluid to drink on the day of your treatment so you stay well hydrated.

Children and adolescents
This medicine should not be given to children and adolescents under 18 years old because it is not known whether it is safe and effective in this age group.

Other medicines and LysaKare
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 taking this medicine.

Driving and using machines
It is considered unlikely that LysaKare will affect your ability to drive or to use machines.

3. How to take LysaKare

The recommended dose of LysaKare solution is 1 L (1,000 mL). You should receive the full LysaKare dose, regardless of any Lutathera dose adjustments.
LysaKare is given as an infusion (drip) into a vein. The infusion of LysaKare will start 30 minutes before you are given Lutathera, and will last over a 4 hour period.

If you receive more LysaKare than you should
LysaKare will be given in a controlled clinical setting and is provided as a single dose bag. It is therefore unlikely that you will receive more of the infusion than you should as your doctor will monitor you during the treatment. However, in the case of an overdose, you will receive the appropriate treatment.

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

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):
- nausea (feeling sick) and vomiting

Not known (frequency cannot be estimated from the available data):
- high potassium levels seen in blood tests, abdominal (belly) pain, headache, dizziness and flushing.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
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 LysaKare

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 after EXP. The expiry date refers to the last day of that month.
LysaKare should be stored below 25°C.

You will not have to store this medicine. The correct storage, use and disposal of this medicine are under the responsibility of the specialist in appropriate premises. You will receive LysaKare in a controlled clinical setting.
The following information is intended for the healthcare specialist charged with your care.
Do not use this medicine:
- if you notice the solution is cloudy or has deposits.
- if overwrap has been previously opened or damaged.
- if the infusion bag is damaged or leaking.

6. Contents of the pack and other information

What LysaKare contains
- The active substances are arginine and lysine.
  Each infusion bag contains 25 g of L-arginine hydrochloride and 25 g of L-lysine hydrochloride.
- The other ingredient is water for injections.

What LysaKare looks like and contents of the pack
LysaKare is a clear and colourless solution for infusion, supplied in a single use flexible plastic bag.
Each infusion bag contains 1 L LysaKare of solution.

Marketing Authorisation Holder
Advanced Accelerator Applications
8-10 Rue Henri Sainte-Claire Deville
92500 Rueil-Malmaison
France

Manufacturer
Laboratoire Bioluz
Zone Industrielle de Jalday
64500 Saint Jean de Luz
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Advanced Accelerator Applications (UK & Ireland) Ltd
Tel: + 44 207 25 85 200

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