Package leaflet: Information for the user

Oxlumo 94.5 mg/0.5 mL solution for injection
lumasiran

▼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 Oxlumo is and what it is used for

What Oxlumo is
Oxlumo contains the active substance lumasiran.

What Oxlumo is used for
Oxlumo is used to treat primary hyperoxaluria type 1 (PH1) in adults and children of all ages.

What PH1 is
PH1 is a rare illness in which the liver produces too much of a substance called oxalate. Your kidneys remove oxalate from the body and it is passed out in the urine. In people with PH1, the extra oxalate can build up in the kidneys and cause kidney stones, and can stop the kidney from working as well as they should. A build-up of oxalate can also damage other parts of the body such as eyes, heart, skin, and bone. This is called oxalosis.

How Oxlumo works
Lumasiran, the active substance in Oxlumo, reduces the amount of an enzyme called glycolate oxidase that the liver makes. Glycolate oxidase is one of the enzymes involved in producing oxalate. By lowering the amount of the enzyme, the liver produces less oxalate and the levels of oxalate in the urine and blood also fall. This can help to reduce the effects of the illness.

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

You must not be given Oxlumo:
- if you are severely allergic to lumasiran, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before you are given this medicine.

Your doctor may monitor you for signs of metabolic acidosis (the build-up of acid in the body).

Other medicines and Oxlumo
Tell your doctor if you are using, have recently used, or might use any other medicines.

Pregnancy
If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or nurse for advice before using this medicine. Your doctor will decide whether you should take Oxlumo after considering the expected health benefits for you as well as the risks to your unborn baby.

Breast-feeding
This medicine may pass into breast milk and it could have an effect on your baby. 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
This medicine is unlikely to have any effect on your ability to drive or use machines.

Oxlumo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

3. How Oxlumo is given

How much Oxlumo is given
Your doctor will work out how much medicine to give you. The dose will depend on how much you weigh. Your doctor will adjust your dose as your weight changes.

You will receive your first doses (loading doses) once a month for 3 months. You will then start maintenance dosing one month after the last loading dose.

<u>Body weight less than 10 kg</u>
- Loading doses: 6 mg for every kg of your weight, given once a month for 3 months.
- Maintenance dosing: 3 mg for every kg of your weight, given once every month.

<u>Body weight from 10 kg to less than 20 kg</u>
- Loading doses: 6 mg for every kg of your weight, given once a month for 3 months.
- Maintenance dosing: 6 mg for every kg of your weight, given once every 3 months.

<u>Body weight 20 kg or more</u>
- Loading doses: 3 mg for every kg of your weight, given once a month for 3 months.
- Maintenance dosing: 3 mg for every kg of your weight, given once every 3 months.

How Oxlumo is given
This medicine will be given to you by a doctor or nurse.
- It is given as an injection under the skin (subcutaneously) into your stomach area (abdomen), or in some cases, your upper arm or thigh. You will be given the injection in a different spot from one injection to the next.
- Depending on your dose, more than one subcutaneous injection may need to be given.
- Your doctor or nurse will not inject into skin areas that are scarred, reddened, inflamed, or swollen.

If you are given too much Oxlumo
In the unlikely event that your doctor or nurse gives you too much (an overdose) they will check you for side effects.

If you miss your dose of Oxlumo
If you miss a dose of Oxlumo, talk to your doctor or nurse as soon as possible about when to get your next dose.

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.

The following side effects may occur when taking Oxlumo:

Very common: may affect more than 1 in 10 people
- Redness, pain, itching, swelling, discomfort, colour changes, mass, induration, rash, bruising or exfoliation at the site of the injection (injection site reaction).
- Stomach pain or discomfort (abdominal pain)

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 the Yellow Card Scheme at 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 Oxlumo

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 carton and vial after EXP. The expiry date refers to the last day of that month.

This medicine is for single use only. Once the vial is opened, use immediately.

Do not store above 30°C.

Keep vial in the outer carton to protect from light.

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxlumo contains
- The active substance is lumasiran.
- Each vial contains lumasiran sodium equivalent to 94.5 mg lumasiran.
- The other ingredients are water for injections, sodium hydroxide, and phosphoric acid (see “Oxlumo contains sodium” in section 2).

What Oxlumo looks like and contents of the pack
This medicine is a clear, colourless-to-yellow solution for subcutaneous injection.

Each pack contains one single use vial containing 0.5 mL solution.

Marketing Authorisation Holder and Manufacturer
Alnylam Netherlands B.V.
Antonio Vivaldistraat 150
1083 HP Amsterdam
Netherlands

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

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Alnylam UK Ltd.
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The following information is intended for healthcare professionals only:

Instructions for use

For subcutaneous use only.

- Collect materials not included in the pack that are needed for administration which will include a sterile syringe (0.3 mL, 1 mL, or 3 mL), an 18-gauge (G) needle, and a 25-G to 31-G needle.
- Calculate the required volume of Oxlumo based on the recommended weight-based dose. If the dose is more than 0.5 mL, you will need to use more than one vial. The maximum acceptable single injection volume to be administered is 1.5 mL. If more than 1.5 mL is needed, you may need to give more than one subcutaneous injection.
- To withdraw Oxlumo, hold the vial upright or tilt at a slight angle and ensure the flat edge of the needle is pointed downwards.
- Point the needle and syringe straight up and tap the syringe to move any bubbles to the top. Once the bubbles are at the top, gently push the plunger to force the bubbles out of the syringe. Check to ensure the correct amount of medicine is in the syringe.
- Administer the medicine with a sterile 25- to 31-G needle with a 13-mm or 16-mm needle length for subcutaneous injection. For volumes less than 0.3 mL, a sterile 0.3-mL syringe is recommended.
- Note: Do not push this medicine into the 25-G to 31-G needle. When using 0.3 mL (insulin) syringes, do not force the bubble from syringe.
- Injection can be into the abdomen, upper arms, or thighs. Consider rotating injection sites. Do not administer into scar tissue or areas that are reddened, inflamed, or swollen.
- Note: When administering subcutaneous injections into the abdomen, avoid a 2.0-cm diameter circle around the navel.
- Clean the area of planned injection with an alcohol swab and wait for the area to dry completely.
- Ensure proper injection technique. Do not inject into a vein or muscle.
- Insert the needle at a right angle (90 degrees) to deliver the injection just below the skin. In patients with little subcutaneous tissue, the needle should be inserted at a 45-degree angle.

- Do not press down on the plunger while piercing the skin. Once the needle is inserted through the skin, release the pinched skin and administer the dose in a slow and steady manner. Once the medicine has been administered count for at least 5 seconds before withdrawing the needle from the skin. Lightly press gauze or cotton ball on the injection site as needed. Do not put the needle cap back on.
- Note: Do not aspirate after inserting the needle to prevent tissue damage, haematoma, and bruising.
- If more than one injection is needed for a single dose of Oxlumo, the injection sites should be at least 2 cm apart.
- Only use the vial once. After administering the dose, dispose of any unused medicine in the vial according to local regulations.
- Use the syringes, transfer needles, and injection needles only once. Dispose of any used syringes and needles in accordance with local regulations.