

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I being given Oxlumo?

Oxlumo contains the active ingredient lumasiran. Oxlumo is used for the treatment of primary hyperoxaluria type 1 (PH1).

For more information, see Section [1. Why am I using Oxlumo?](#) in the full CMI.

### 2. What should I know before I am given Oxlumo?

Do not take if you have ever had an allergic reaction to Oxlumo or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Oxlumo?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Oxlumo and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given Oxlumo?

- Your doctor will determine the appropriate dose based on your body weight and phase of treatment.
- Oxlumo is given as a subcutaneous (under the skin) injection.
- The Oxlumo injection should be given to you by a trained healthcare professional.

More instructions can be found in Section [4. How do I use Oxlumo?](#) in the full CMI.

### 5. What should I know while being given Oxlumo?

Things you should do	<ul style="list-style-type: none"><li>• Tell your doctor if you are pregnant or breastfeeding, or planning to become pregnant.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using Oxlumo.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Your doctor will tell you how long you need to receive Oxlumo. Do not stop treatment with Oxlumo unless your doctor tells you to.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Oxlumo has no or negligible influence on the ability to drive or use machines.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Your doctor or nurse will store your medicine until it is needed.</li></ul>

For more information, see Section [5. What should I know while using Oxlumo?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include stomach pain, or redness, swelling, pain, itching, rash or bruising at the injection site.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# OXLUMO

Active ingredient(s): *lumasiran*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxlumo. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Oxlumo.

### Where to find information in this leaflet:

- [1. Why am I being given Oxlumo?](#)
- [2. What should I know before I am given Oxlumo?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Oxlumo?](#)
- [5. What should I know while being given Oxlumo?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given Oxlumo?

Oxlumo contains the active ingredient lumasiran. Oxlumo is small interfering ribonucleic acid (siRNA) that targets the body's oxalate production processes. This reduces the oxalate levels in urine and plasma which can cause damage to the kidneys and other organs.

Oxlumo is used for the treatment of a condition called primary hyperoxaluria type 1 (PH1) in adults and children.

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.

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 should I know before I am given Oxlumo?

#### Warnings

##### Do not take Oxlumo if:

- you are allergic to lumasiran, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

##### Check with your doctor if you:

- have any other medical conditions
- have severe or end-stage kidney impairment or moderate to severe liver disease
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Oxlumo.

### 4. How will I be given Oxlumo?

#### How is Oxlumo given?

- Oxlumo is administered as a subcutaneous (under the skin) injection.
- The Oxlumo injection should be given to you by a trained healthcare professional.

## How much will be given?

- Your doctor will calculate the dose for you based on your body weight and phase of treatment

## When will I be given Oxlumo?

- Initially you will be given Oxlumo once a month, which may reduce in frequency after 3 months of treatment.

## If you forget to use Oxlumo

Oxlumo should be used regularly. If you miss your appointment to receive Oxlumo at the usual time, your doctor should provide the next dose of Oxlumo as soon as possible.

## If you are given too much Oxlumo

Oxlumo will be given to you by trained hospital personnel. In the unlikely event that you are given too much Oxlumo (an overdose), your doctor or nurse will check you for side effects.

However, if you think that you have received too much Oxlumo, tell your doctor or nurse immediately as you may need urgent medical attention.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while being given Oxlumo?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Oxlumo.

Tell your doctor if you are planning to become pregnant.

### Things you should not do

**Your doctor will tell you how long you need to receive Oxlumo. Do not stop treatment with Oxlumo unless your doctor tells you to.**

### Driving or using machines

Oxlumo has no or negligible effect on your ability to drive or use machines.

### Looking after your medicine

- Your doctor or nurse will look after your medicine until it is needed.

### Getting rid of any unwanted medicine

Your doctor or nurse will throw away any medicines that are no longer being used.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Stomach related:</b></p> <ul style="list-style-type: none"><li>• Stomach pain, discomfort or tenderness</li></ul> <p><b>Local reaction (injection site):</b></p> <ul style="list-style-type: none"><li>• Redness of the skin</li><li>• Swelling</li><li>• Pain</li><li>• Itching</li><li>• Rash</li><li>• Bruising</li></ul> <p><b>Immune system related:</b></p> <ul style="list-style-type: none"><li>• A type of allergic reaction (hypersensitivity) – with symptoms such as rash, throat irritation, and watery eyes.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Oxlumo contains

Active ingredient (main ingredient)	Lumasiran
Other ingredients (inactive ingredients)	Sodium hydroxide Phosphoric acid

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Oxlumo looks like**

Oxlumo is a clear, colourless to yellow solution.

Oxlumo is provided in a clear glass vial with a rubber stopper and aluminium seal.

Each vial of Oxlumo contains 0.5 mL of solution for injection.

AUST R 421050.

### **Who is the sponsor for Oxlumo**

Medison Pharma Australia Pty Ltd

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