Package leaflet: Information for the patient

Lucentis 10 mg/ml solution for injection in pre-filled syringe
ranibizumab

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.
- 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 Lucentis is and what it is used for

What Lucentis is
Lucentis is a solution which is injected into the eye. Lucentis belongs to a group of medicines called antineovascularisation agents. It contains the active substance called ranibizumab.

What Lucentis is used for
Lucentis is used in adults to treat several eye diseases causing vision impairment.

These diseases result from damage to the retina (light-sensitive layer at the back of the eye) caused by:
- Growth of leaky, abnormal blood vessels. This is observed in diseases such as age-related macular degeneration (AMD) and proliferative diabetic retinopathy (PDR, a disease caused by diabetes). It may also be associated with choroidal neovascularisation (CNV) due to pathologic myopia (PM), angioid streaks, central serous chorioretinopathy or inflammatory CNV.
- Macular oedema (swelling of the centre of the retina). This swelling can be caused by diabetes (a disease called diabetic macular oedema (DME)) or by the blockage of retinal veins of the retina (a disease called retinal vein occlusion (RVO)).

How Lucentis works
Lucentis specifically recognises and binds to a protein called human vascular endothelial growth factor A (VEGF-A) present in the eye. In excess, VEGF-A causes abnormal blood vessel growth and swelling in the eye which can lead to impairment of vision in diseases like AMD, DME, PDR, RVO, PM and CNV. By binding to VEGF-A, Lucentis can block its actions and prevent this abnormal growth and swelling.

In these diseases, Lucentis can help to stabilise and in many cases improve your vision.

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

You must not receive Lucentis
- If you are allergic to ranibizumab or any of the other ingredients of this medicine (listed in section 6).
- If you have an infection in or around your eye.
- If you have pain or redness (severe intraocular inflammation) in your eye.

Warnings and precautions
Talk to your doctor before you are given Lucentis.
- Lucentis is given as an injection into the eye. Occasionally, an infection in the internal portion of the eye, pain or redness (inflammation), detachment or tear of one of the layers in the back of the eye (retinal detachment or tear and retinal pigment epithelial detachment or tear), or clouding of the lens (cataract) may occur after Lucentis treatment. It is important to identify and treat such an infection or retinal detachment as soon as possible. Please tell your doctor immediately if you develop signs such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in your vision or increased sensitivity to light.
- In some patients the eye pressure may increase for a short period directly after the injection. This is something you may not notice, therefore your doctor may monitor this after each injection.
- Inform your doctor if you have a prior history of eye conditions or eye treatments, or if you have had a stroke or experienced transient signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding). This information will be taken into account to evaluate if Lucentis is the appropriate treatment for you.

Please see section 4 ("Possible side effects") for more detailed information on side effects that could occur during Lucentis therapy.

Children and adolescents (below 18 years of age)
The use of Lucentis in children and adolescents has not been established and is therefore not recommended.

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

Pregnancy and breast-feeding
- Women who could become pregnant must use effective contraception during treatment and for at least three further months after the last injection of Lucentis.
- There is no experience of using Lucentis in pregnant women. Lucentis should not be used during pregnancy unless the potential benefit outweighs the potential risk to the unborn child. If you are pregnant, think you may be pregnant or planning to become pregnant, discuss this with your doctor before treatment with Lucentis.
- Small amounts of Lucentis may pass into breast milk, therefore Lucentis is not recommended during breast-feeding. Ask your doctor or pharmacist for advice before Lucentis treatment.

Driving and using machines
After Lucentis treatment you may experience some temporary vision blurring. If this happens, do not drive or use machines until this resolves.

3. How Lucentis is given

Lucentis is administered as a single injection into your eye by your eye doctor under a local anaesthetic. The usual dose of an injection is 0.05 ml (which contains 0.5 mg of active substance). The pre-filled syringe contains more than the recommended dose of 0.5 mg. The extractable volume is not to be used in total. The excess volume should be expelled prior to injection. Injecting the entire volume of the pre-filled syringe could result in overdose.

The interval between two doses injected into the same eye should be at least four weeks. All injections will be administered by your eye doctor.

Before the injection, your doctor will wash your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

The treatment is started with one injection of Lucentis per month. Your doctor will monitor the condition of your eye and, depending on how you respond to the treatment, will decide if and when you need to receive further treatment.

Detailed instructions for use are given at the end of the leaflet under "How to prepare and administer Lucentis".

Elderly (age 65 years and over)
Lucentis can be used for people of 65 years of age and over without dose adjustment.

Before stopping Lucentis treatment
If you are considering stopping Lucentis treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Lucentis.

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.

The side effects associated with the administration of Lucentis are either due to the medicine itself or the injection procedure and mostly affect the eye.

The most serious side effects are described below:
Common serious side effects (may affect up to 1 in 10 people): Detachment or tear of the layer in the back of the eye (retinal detachment or tear), resulting in flashes of light with floaters progressing to a temporary loss of sight, or a clouding of the lens (cataract).
Uncommon serious side effects (may affect up to 1 in 100 people): Blindness, infection of the eyeball (endophthalmitis) with inflammation of the inside of the eye.

The symptoms you might experience are pain or increased discomfort in your eye, worsening eye redness, blurred or decreased vision, an increased number of small particles in your vision or increased sensitivity to light. **Please tell your doctor immediately if you develop any of these side effects**.

The most frequently reported side effects are described below:
Very common side effects (may affect more than 1 in 10 people)
Visual side effects include: Inflammation of the eye, bleeding in the back of the eye (retinal bleeding), visual disturbances, eye pain, small particles or spots in your vision (floaters), bloodshot eye, eye irritation, a feeling of having something in the eye, increased tear production, inflammation or infection of the eyelid margins, dry eye, redness or itching of the eye and increased eye pressure.
Non-visual side effects include: Sore throat, nasal congestion, runny nose, headache and joint pain.

Other side effects which may occur following Lucentis treatment are described below:
Common side effects
Visual side effects include: Decreased sharpness of vision, swelling of a section of the eye (uvea, cornea), inflammation of the cornea (front part of eye), small marks on the surface of the eye, blurred vision, bleeding at the site of injection, bleeding in the eye, discharge from the eye with itching, redness and swelling (conjunctivitis), light sensitivity, eye discomfort, swelling of the eyelid, eyelid pain.
Non-visual side effects include: Urinary tract infection, low red blood cells count (with symptoms such as tiredness, breathlessness, dizziness, pale skin), anxiety, cough, nausea, allergic reactions like rash, hives, itching and skin reddening.

Uncommon side effects
Visual side effects include: Inflammation and bleeding in the front part of the eye, sac of pus on the eye, changes of the central part of the eye surface, pain or irritation at the site of injection, abnormal sensation in the eye, irritation of the eyelid.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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

5. How to store Lucentis

- 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 pre-filled syringe label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C – 8°C). Do not freeze.
- Prior to use, the sealed tray may be kept at room temperature (25°C) for up to 24 hours.
- Keep the pre-filled syringe in its unopened tray in the carton in order to protect from light.
- Do not use any pack that is damaged.

6. Contents of the pack and other information

What Lucentis contains
- The active substance is ranibizumab. Each ml contains 10 mg ranibizumab. One pre-filled syringe contains 0.165 ml, equivalent to 1.65 mg ranibizumab. This provides a usable amount to deliver a single dose of 0.05 ml containing 0.5 mg ranibizumab.
- The other ingredients are α,α-trehalose dihydrate; histidine hydrochloride, monohydrate; histidine; polysorbate 20; water for injections.

What Lucentis looks like and contents of the pack
Lucentis is a solution for injection in a pre-filled syringe. The pre-filled syringe contains 0.165 ml of a sterile, clear, colourless to pale brownish-yellow aqueous solution. The pre-filled syringe contains more than the recommended dose of 0.5 mg. The extractable volume is not to be used in total. The excess volume should be expelled prior to injection. Injecting the entire volume of the pre-filled syringe could result in overdose.

Pack size of one pre-filled syringe, packed in a sealed tray. The pre-filled syringe is for single use only.

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

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu

The following information is intended for healthcare professionals only:

Please also refer to section 3 “How Lucentis is given”.

How to prepare and administer Lucentis

Single-use pre-filled syringe for intravitreal use only

Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections.

In wet AMD, in CNV, in PDR and in visual impairment due to DME or to macular oedema secondary to RVO the recommended dose for Lucentis is 0.5 mg given as a single intravitreal injection. This corresponds to an injection volume of 0.05 ml. The interval between two doses injected into the same eye should be at least four weeks.

Treatment is initiated with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity i.e. no change in visual acuity and in other signs and symptoms of the disease under continued treatment. In patients with wet AMD, DME, PDR and RVO, initially, three or more consecutive, monthly injections may be needed.

Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity, as assessed by visual acuity and/or anatomical parameters.

If, in the physician’s opinion, visual and anatomical parameters indicate that the patient is not benefiting from continued treatment, Lucentis should be discontinued.

Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein angiography).

If patients are being treated according to a treat-and-extend regimen, once maximum visual acuity is achieved and/or there are no signs of disease activity, the treatment intervals can be extended stepwise until signs of disease activity or visual impairment recur. The treatment interval should be extended by no more than two weeks at a time for wet AMD and may be extended by up to one month at a time for DME. For PDR and RVO, treatment intervals may also be gradually extended, however there are insufficient data to conclude on the length of these intervals. If disease activity recurs, the treatment interval should be shortened accordingly.

The treatment of visual impairment due to CNV should be determined individually per patient based on disease activity. Some patients may only need one injection during the first 12 months; others may need more frequent treatment, including a monthly injection. For CNV secondary to pathologic myopia (PM), many patients may only need one or two injections during the first year.

Lucentis and laser photocoagulation in DME and macular oedema secondary to BRVO
There is some experience of Lucentis administered concomitantly with laser photocoagulation. When given on the same day, Lucentis should be administered at least 30 minutes after laser photocoagulation. Lucentis can be administered in patients who have received previous laser photocoagulation.

Lucentis and verteporfin photodynamic therapy in CNV secondary to PM
There is no experience of concomitant administration of Lucentis and verteporfin.

Lucentis should be inspected visually for particulate matter and discoloration prior to administration.

The injection procedure should be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent) and the availability of sterile paracentesis (if required). The patient’s medical history for hypersensitivity reactions should be carefully evaluated prior to performing the intravitreal procedure.

Adequate anaesthesia and a broad-spectrum topical microbicide to disinfect the periocular skin, eyelid and ocular surface should be administered prior to the injection, in accordance with local practice.

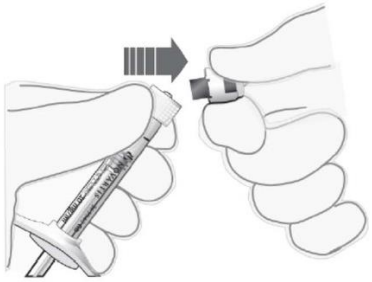
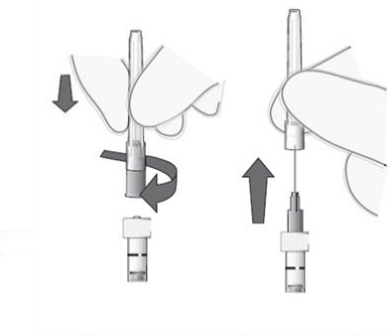
The pre-filled syringe is for single use only. The pre-filled syringe is sterile. Do not use the product if the packaging is damaged. The sterility of the pre-filled syringe cannot be guaranteed unless the tray remains sealed. Do not use the pre-filled syringe if the solution is discoloured, cloudy or contains particles.

The pre-filled syringe contains more than the recommended dose of 0.5 mg. The extractable volume of the pre-filled syringe (0.1 ml) is not to be used in total. The excess volume should be expelled prior to injection. Injecting the entire volume of the pre-filled syringe could result in overdose. To expel the air bubble along with the excess medicinal product, slowly push the plunger until the edge below the dome of the rubber stopper is aligned with the black dosing line on the syringe (equivalent to 0.05 ml, i.e., 0.5 mg ranibizumab).

For the intravitreal injection, a 30G x ½″ sterile injection needle should be used.

To prepare Lucentis for intravitreal administration, please adhere to the instructions for use:

<table>
<tr><td>Introduction</td><td colspan="2">Read all the instructions carefully before using the pre-filled syringe.
The pre-filled syringe is for single use only. The pre-filled syringe is sterile. Do not use the product if the packaging is damaged. The opening of the sealed tray and all subsequent steps should be done under aseptic conditions.
Note: The dose must be set to 0.05 ml.</td></tr>
<tr><td>Pre-filled syringe description</td><td colspan="2">Syringe cap 0.05 ml dose mark Finger grip
 
Luer lock Rubber stopper Plunger rod
Figure 1</td></tr>
<tr><td>Prepare</td><td colspan="2">1. Make sure that the pack contains:
• a sterile pre-filled syringe in a sealed tray.
2. Peel the lid off the syringe tray and, using aseptic technique, carefully remove the syringe.</td></tr>
<tr><td>Check syringe</td><td>3. Check that:
• the syringe cap is not detached from the Luer lock.
• the syringe is not damaged.
• the solution looks clear, colourless to pale brownish-yellow and does not contain any particles.
4. If any of the above is not true, discard the pre-filled syringe and use a new one.</td><td></td></tr>
</table>

Remove syringe cap	5. Snap off (do not turn or twist) the syringe cap (see Figure 2). 6. Dispose of the syringe cap (see Figure 3).	 **Figure 2**  **Figure 3**
Attach needle	7. Attach a 30G x ½″ sterile injection needle firmly onto the syringe by screwing it tightly onto the Luer lock (see Figure 4). 8. Carefully remove the needle cap by pulling it straight off (see Figure 5). **Note: Do not wipe the needle at any time.**	 **Figure 4** **Figure 5**

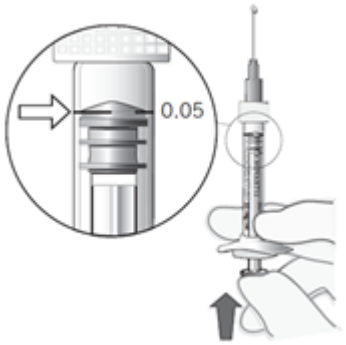
<table>
<tr><td>Dislodge air bubbles</td><td>9. Hold the syringe upright.
10. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see Figure 6).</td><td> 
Figure 6</td></tr>
<tr><td>Set dose</td><td>11. Hold the syringe at eye level and carefully push the plunger until the edge below the dome of the rubber stopper is aligned with the dose mark (see Figure 7). This will expel the air and the excess solution and set the dose to 0.05 ml.
Note: The plunger rod is not attached to the rubber stopper – this is to prevent air being drawn into the syringe.</td><td> 

Figure 7</td></tr>
<tr><td>Inject</td><td colspan="2">The injection procedure should be carried out under aseptic conditions.
12. The injection needle should be inserted 3.5-4.0 mm posterior to the limbus into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe.
13. Inject slowly until the rubber stopper reaches the bottom of the syringe to deliver the volume of 0.05 ml.
14. A different scleral site should be used for subsequent injections.
15. After injection, do not recap the needle or detach it from the syringe. Dispose of the used syringe together with the needle in a sharps disposal container or in accordance with local requirements.</td></tr>
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