A brief guide to the management of risks associated with intravitreal injections during Lucentis® treatment

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PHARMACEUTICALS

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DESIGNED TO SAVE SIGHT

Physician leaflet

This physician leaflet is part of the educational materials regarding the use of Lucentis® (ranibizumab) and provides information on the method of administration of Lucentis® and on the prevention and management of risks associated with intravitreal injections.

Complete information regarding the safety profile of Lucentis® is detailed within the Summary of Product Characteristics.[1]

Prevention and management of key injection-related risks with Lucentis®

Intravitreous injections, including those with Lucentis®, have been associated with

- endophthalmitis
- intraocular inflammation
- rhegmatogenous retinal detachment
- retinal tear
- traumatic cataract

Proper aseptic injection techniques must always be used when administering Lucentis®. In addition, patients should be monitored during the week following the injection to permit early treatment if an infection occurs. Patients should be informed of symptoms of these potential adverse reactions and instructed to inform their physician without delay if they develop signs such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in their vision, or increased sensitivity to light.

Endophthalmitis

Characteristics

- Endophthalmitis is a serious ocular condition consisting of inflammation of the vitreous cavity and can potentially lead to blindness[2]
- Endophthalmitis is often caused by an intraocular infection
  - Frequently implicated pathogens include skin bacteria such as coagulase-negative staphylococci, *Staphylococcus aureus* and streptococci[2]
  - *Streptococcus viridans* (a commensal organism of the throat) has been isolated over three times more frequently in cases of endophthalmitis occurring after intravitreal injection than after intraocular surgery[3]
- Events such as penetrating trauma, surgical procedures and intravitreal injections that disrupt the integrity of the eye globe can potentially lead to endophthalmitis[2]
- Endophthalmitis following Lucentis® injection is uncommon and the reported incidence in Lucentis® clinical trials ranges from ≥1/1,000 to <1/100 patients across all indications[1]

Prevention and management

- Lucentis® should be prepared for intravitreal injection and administered according to the steps outlined in the Summary of Product Characteristics and summarized on page 10 of this leaflet
  - It is essential to perform the injection procedure under aseptic conditions to prevent contamination of the eye
  - 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) is recommended[1]
- Patients should be instructed to inform their physician immediately if they develop signs such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of floating shadows, dots or particles in their visual field, or increased sensitivity to light[1]
- The pre-filled syringe is for single use only. Use of more than one injection from a pre-filled syringe can lead to contamination and subsequent infection
- Appropriate management and treatment of endophthalmitis should be followed according to local clinical practice

Cataract

Characteristics

- Traumatic cataract can be caused by trauma to the intraocular lens following either penetrating or non-penetrating ocular trauma
- Cataract may lead to loss of vision, and may require surgical intervention[4]

Prevention and management

- To reduce the risk of traumatic cataract, it is essential that Lucentis® is prepared for intravitreal injection and administered according to the steps outlined in the Summary of Product Characteristics and summarized on pages 10 and 11 of this leaflet[1]
  - Care should be taken to ensure the injection is inserted 3.5-4.0 mm posterior to the limbus into the vitreous cavity, avoiding the horizontal meridian and aiming towards the center of the globe, avoiding contact with the lens
- Patients should be instructed to inform their physician immediately if they develop symptoms such as sudden blurred or decreased vision[1]
- Appropriate management and treatment of traumatic cataract should be followed according to local clinical practice

Increases in intraocular pressure

Characteristics

- Increases in IOP within 60 minutes of injection of Lucentis® are very common and the reported incidence is ≥1/10 patients in Lucentis® clinical trials across all indications[1]
- Increases in IOP are caused by injection of fluid into the eye and are more likely if high volumes are administered
- Post-injection increases in IOP are often asymptomatic and usually resolve quickly (are transient)

Prevention and management

- Lucentis® should be administered as a single intravitreal injection with an injection volume of 0.05 mL
  - Injection volume should be accurately checked to minimize the risk of increases in IOP
  - If an overdose occurs, IOP should be monitored and treated, if deemed necessary by the attending physician[1]
- IOP and perfusion of the optic nerve head must be monitored and managed appropriately[1]
  - The treatment of increases in IOP should follow local clinical practice
- Paracentesis should only be carried out in cases in which the degree of increase in IOP poses a threat to vision[5]

Overdose due to overfill of the pre-filled syringe

Characteristics

- The pre-filled syringe contains more Lucentis® solution than is required for a single dose
- The extra volume is present to aid priming the needle and syringe in preparation for the injection

Prevention and management

- The instructions for use in the Summary of Product Characteristics, summarized on pages 10 and 11 of this leaflet, should be closely followed to ensure accurate setting of the dose in the syringe[1]
- If an overdose occurs, IOP should be monitored and treated, if deemed necessary by the physician
- IOP and perfusion of the optic nerve head should be monitored and managed appropriately
- Paracentesis should only be carried out in cases in which the degree of increase in IOP poses a threat to vision

Administration of Lucentis®

- Lucentis® is available as either a vial kit or pre-filled syringe
- Lucentis® should be inspected visually for particulate matter and discoloration prior to administration
- Both the vial kit and the pre-filled syringe are for single use only. Lucentis® is not licensed for multi-dose, further compounding or vial splitting. Use of more than one injection from the vial can lead to contamination and subsequent infection
- The injection procedure should be carried out under aseptic conditions:
  - The use of surgical hand disinfection, sterile gloves, a sterile drape and sterile eyelid speculum (or equivalent) is recommended
  - The periocular skin, eyelid and ocular surface should be disinfected
- Adequate anesthesia and broad-spectrum topical microbicide should be administered prior to the injection
- Prophylactic topical antibiotics should be used according to local clinical practice
- The patient's medical history should be carefully evaluated for hypersensitivity reactions prior to performing the intravitreal procedure

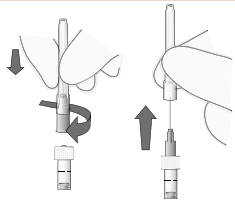
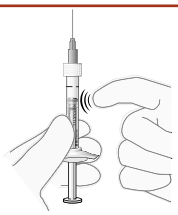
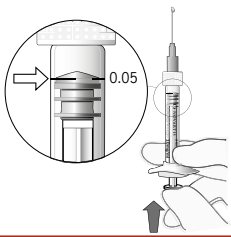
References

1. Novartis Pharma AG. Lucentis® Summary of Product Characteristics.
2. Kernt M, Kampik A. Endophthalmitis: pathogenesis, clinical presentation, management, and perspectives. *Clin Ophthalmol* 2010;4:121–135.
3. Chen E, Lin MY, Cox J, Brown DM. Endophthalmitis after intravitreal injection: the importance of viridans streptococci. *Retina* 2011;31:1525–1533.
4. Thylefors B. Epidemiological patterns of ocular trauma. *Aust N Z J Ophthalmol* 1992;20:95–98.
5. Aiello LP, Brucker AJ, Chang S *et al.* Evolving guidelines for intravitreous injections. *Retina* 2004;24:S3–S19.

Preparation of Lucentis® for intravitreal injection using the pre-filled syringe

To prepare Lucentis® for intravitreal administration, please adhere to the instructions for use. To prepare the Lucentis® pre-filled syringe for intravitreal administration, please adhere to the following instructions:

The single-use pre-filled syringe is for intravitreal use only. 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.

Introduction	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.**
Pre-filled syringe description	 Figure 1
Prepare	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.
Check syringe	3. Check that: – the syringe cap is not detached from the Luer lock. – the syringe is not damaged. – the solution looks clear, colorless to pale 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.
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 30-gauge x ½-inch 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
Dislodge air bubbles	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**).  Figure 6
Set dose	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.**  Figure 7
Inject	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 center 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.

Preparation of Lucentis® for intravitreal injection using the vial kit

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

The vial kit is for single use only. Lucentis® is not licensed for multi-dose, further compounding or vial splitting. Use of more than one injection from the vial can lead to contamination and subsequent infection.

All components are sterile and for single use only. Any component with packaging showing signs of damage or tampering must not be used. The sterility cannot be guaranteed unless the component packaging seal remains intact. Re-use may lead to infection or other illness/injury.

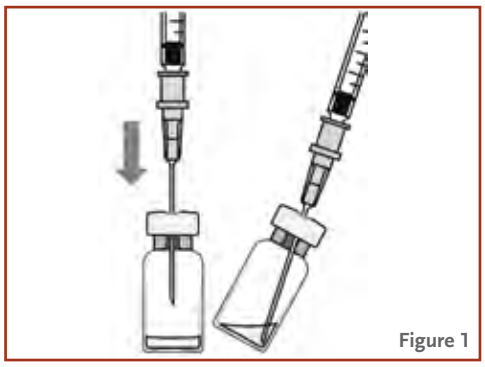


Figure 1

1. Before withdrawal, the outer part of the rubber stopper of the vial should be disinfected.
2. Assemble a 5 µm filter needle (18-gauge) onto the 1 mL syringe using aseptic technique. Push the blunt filter needle into the center of the vial stopper until the needle touches the bottom edge of the vial.
3. Withdraw all the liquid from the vial, keeping the vial in an upright position, slightly inclined to ease complete withdrawal (**Figure 1**).

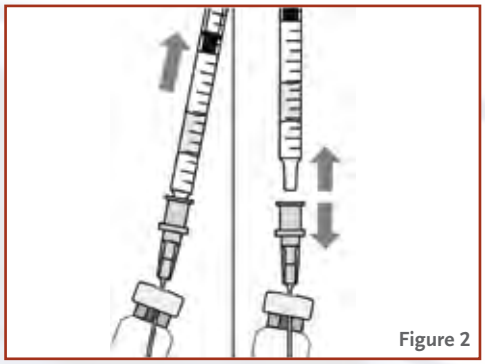


Figure 2

4. Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle.
5. Leave the blunt filter needle in the vial and disconnect the syringe from the blunt filter needle. The filter needle should be discarded after withdrawal of the vial contents and should not be used for the intravitreal injection (**Figure 2**).

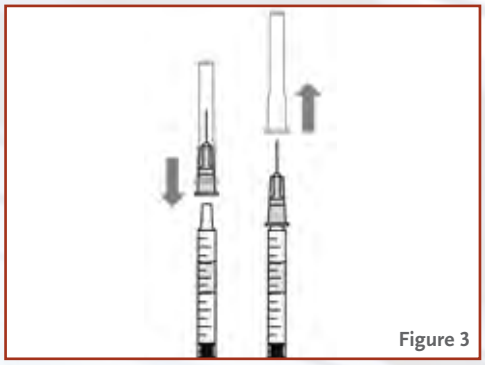


Figure 3

6. Aseptically and firmly assemble the injection needle (30-gauge x ½-inch) onto the syringe.
7. Carefully remove the cap from the injection needle without disconnecting the injection needle from the syringe (**Figure 3**).

   Note: grip at the yellow hub of the injection needle while removing the cap.

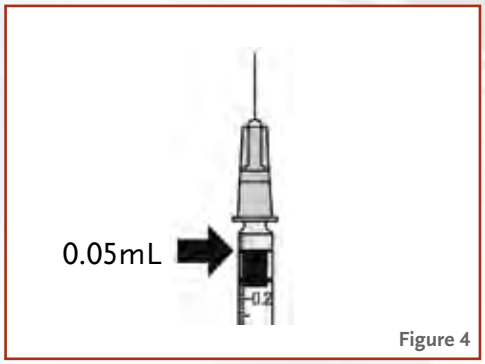


Figure 4

8. Carefully expel the air from the syringe and adjust the dose to the 0.05 mL mark on the syringe (**Figure 4**). The syringe is ready for injection.

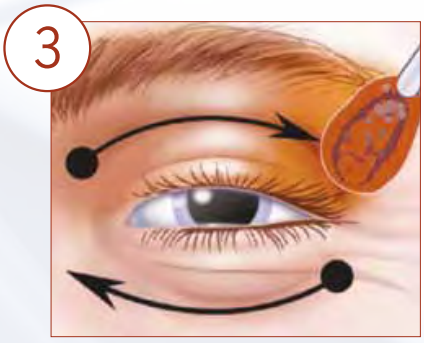
   Note: do not wipe the injection needle. Do not pull back on the plunger.

   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 center of the globe. The injection volume of 0.05 mL is then delivered; a different scleral site should be used for subsequent injections.

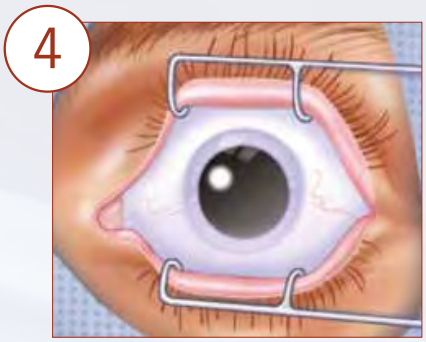
After injection, do not recap the needle or detach it from the syringe. Dispose of the used syringe together with the needle in a sharps disposal container or in accordance with local requirements.

Preparation of the eye and administration of Lucentis®

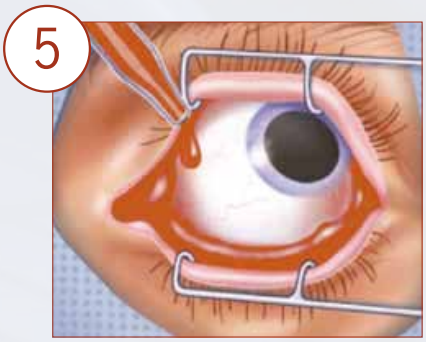
1. Dilate the pupil.
2. Apply topical anesthesia.



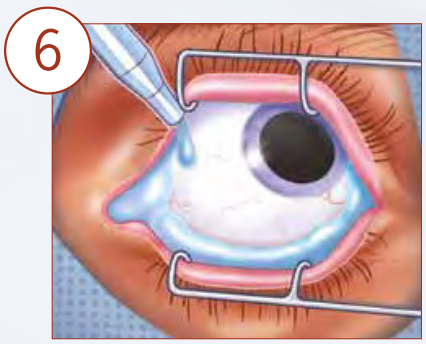
3. Apply 10% povidone iodine solution to periocular skin, lids and eyelashes, and place sterile drape over eye.



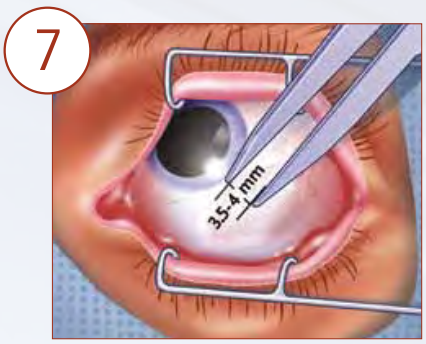
4. Apply sterile lid speculum.



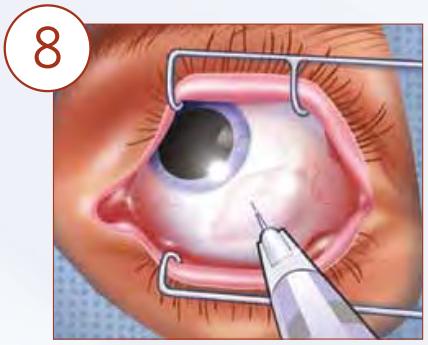
5. Instill 5% povidone iodine ophthalmic solution, and wait for 90 seconds.



6. Rinse the eye with ophthalmic saline solution.



7. Direct the patient to look away from the injection site. Mark an injection site at an area 3.5-4.0 mm posterior to the limbus, avoiding the horizontal meridian and aiming toward the center of the globe.



8. Slowly deliver the injection volume, then remove the needle slowly.
   – Rotate the scleral site for subsequent intravitreal injections so that the same site is not injected repeatedly.

Note: prophylactic topical antibiotics should be used according to local clinical practice

Lucentis® 10mg/ml pre-filled syringe

PRESENTATION: 10mg/ml solution for injection in pre-filled syringe. Each vial contains 2.3 mg of ranibizumab in 0.23 ml solution. **INDICATIONS:** The treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM) **DOSAGE:** Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections.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 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. *Lucentis and laser photocoagulation in DME and in macular oedema secondary to BRVO:* When given on the same day, Lucentis should be administered at least 30 minutes after laser photocoagulation. *Hepatic impairment:* Lucentis has not been studied in patients with hepatic impairment. However, no special considerations are needed in this population. *Renal impairment:* Dose adjustment is not needed in patients with renal impairment. *Elderly:* No dose adjustment is required in the elderly. *Paediatric population:* The safety and efficacy of Lucentis in children and adolescents below 18 years of age have not been established. C**ONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. Patients with active or suspected ocular or periocular infections. Patients with active severe intraocular inflammation **WARNINGS/PRECAUTIONS:** *Intravitreal injection-related reactions*: Intravitreous injections, including those with Lucentis, have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Proper aseptic injection techniques must always be used when administering Lucentis. *Intraocular pressure increases:* Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of injection of Lucentis. Sustained IOP increases have also been identified. Both intraocular pressure and the perfusion of the optic nerve head must be monitored and managed appropriately. *Bilateral treatment:* Limited data on bilateral use of Lucentis (including same-day administration) do not suggest an increased risk of systemic adverse events compared with unilateral treatment. *Immunogenicity:* There is a potential for immunogenicity with Lucentis. Since there is a potential for an increased systemic exposure in subjects with DME, an increased risk for developing hypersensitivity in this patient population cannot be excluded. Patients should also be instructed to report if an intraocular inflammation increases in severity, which may be a clinical sign attributable to intraocular antibody formation. *Concomitant use of other anti-VEGF (vascular endothelial growth factor):* Lucentis should not be administered concurrently with other anti-VEGF medicinal products (systemic or ocular). *Withholding Lucentis:* The dose should be withheld and treatment should not be resumed earlier than the next scheduled treatment in the event of: ●a decrease in best-corrected visual acuity (BCVA) of ≥30 letters compared with the last assessment of visual acuity; ● an intraocular pressure of ≥30 mmHg; ● a retinal break; ● a subretinal haemorrhage involving the centre of the fovea, or, if the size of the haemorrhage is ≥50%, of the total lesion area; ● performed or planned intraocular surgery within the previous or next 28 days. *Retinal pigment epithelial tear:* Risk factors associated with the development of a retinal pigment epithelial tear after anti-VEGF therapy for wet AMD, include a large and/or high pigment epithelial retinal detachment. When initiating Lucentis therapy, caution should be used in patients with these risk factors for retinal pigment epithelial tears. *Rhegmatogenous retinal detachment or macular holes:* Treatment should be discontinued in subjects with rhegmatogenous retinal detachment or stage 3 or 4 macular holes. *Systemic effects following intravitreal use:* Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors. *Women of childbearing potential/contraception in females:* Women of childbearing potential should use effective contraception during treatment. *Pregnancy:* For women who wish to become pregnant and have been treated with ranibizumab, it is recommended to wait at least 3 months after the last dose of ranibizumab before conceiving a child. *Breast-feeding:* It is unknown whether Lucentis is excreted in human milk. Breast-feeding is not recommended during the use of Lucentis. *Effects on ability to drive and use machines:* The Lucentis treatment procedure may induce temporary visual disturbances, which may affect the ability to drive or use machines (see section 4.8). Patients who experience these signs must not drive or use machines until these temporary visual disturbances subside. **INTERACTIONS:** No formal interaction studies have been performed. **ADVERSE REACTIONS:** *Very common:* Nasopharyngitis. Headache. Vitritis, vitreous detachment, retinal haemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival haemorrhage, eye irritation, foreign body sensation in eyes, lacrimation increased, blepharitis, dry eye, ocular hyperaemia, eye pruritus. Arthralgia. Intraocular pressure increased. *Common:* Urinary tract infection. Anaemia. Hypersensitivity. Anxiety. Retinal degeneration, retinal disorder, retinal detachment, retinal tear, detachment of the retinal pigment epithelium, retinal pigment epithelium tear, visual acuity reduced, vitreous haemorrhage, vitreous disorder, uveitis, iritis, iridocyclitis, cataract, cataract subcapsular, posterior capsule opacification, punctuate keratitis, corneal abrasion, anterior chamber flare, vision blurred, injection site haemorrhage, eye haemorrhage, conjunctivitis, conjunctivitis allergic, eye discharge, photopsia, photophobia, ocular discomfort, eyelid oedema, eyelid pain, conjunctival hyperaemia. Cough. Nausea. Allergic reactions (rash, urticaria, pruritus, erythema). *Please refer to the Summary of Product Characteristics for a full list of adverse events.* **LEGAL CATEGORY:** POM **PACK SIZES**: one pre-filled syringe, packed in a sealed tray **MARKETING AUTHORISATION HOLDER**: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom **MARKETING AUTHORISATION NUMBERS**: EU/1/06/374/003 **Please refer to Summary of Product Characteristics (SmPC) before prescribing**. Full prescribing information is available on request from Novartis Pharma Services Inc., Representative Office Malta, P.O. Box 4, MRS 1000, Marsa, Malta. Tel+35621222872. 2015-LUCP-28-AUG-2015

Lucentis® 10mg/ml solution for injection

PRESENTATION: A glass single-use vial containing: 0.23ml solution - 2.3mg of ranibizumab (10mg/ml). **INDICATIONS**: Lucentis is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD), the treatment of visual impairment due to diabetic macular oedema (DME), the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO (see section 5.1) and the treatment of visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM). **DOSAGE AND ADMINISTRATION**: Single-use vial for intravitreal use only. Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections under aseptic conditions. 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 recommended dose is 0.5mg (0.05ml) vial per month until maximum visual acuity is achieved and/or there are no signs of disease acitivity i.e. no change in visual acuity and in other signs and symptoms of the disease under continued treatment. The interval between two doses should not be shorter than 1 month. For wet AMD, DME and RVO, initially, 3 or more consecutive, monthly injections may be needed. Before treatment, evaluate the patients medical history for hypersensitivity. If there is no improvement in visual acuity, continued treatment is not recommended. Thereafter patients should be monitored monthly for visual acuity. Treatment is resumed when monitoring indicates loss of visual acuity due to wet AMD, DME or to macular oedema secondary to RVO. . For cases of visual impairment due to CNV secondary to PM, many patients will only need one to two injections during the first year. If monitoring reveals signs of disease activity, further treatment is recommended. **Paediatric population:** The safety and efficacy of Lucentis in children and adolescents below 18 years of age have not been established. No data are available.. Renal Impairment and **Elderly:** No dose adjustment is required. There is limited experience in patients older than 75 years with DME. Consult SmPC for full administration details before using Lucentis. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Patients with active or suspected ocular or periocular infections. Patients with active severe intraocular inflammation. **WARNINGS/PRECAUTIONS:** Lucentis is for intravitreal injection only. Intravitreous injections have been associated with endophthalmitus, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Monitor during week following injection for infections. Patients should be instructed to report symptoms suggestive of any of the above without delay. Transient increases in intraocular pressure (IOP) have been seen within 1 hour of injection. Sustained IOP increases have also been identified. Both intraocular pressure and perfusion of the optic nerve head must be monitored and managed appropriately. Concurrent use in both eyes has not been studied. Limited data on bilateral use of Lucentis (including same-day administration) do not suggest an increased risk of systemic adverse events compared with unilateral treatment. There is a potential for immunogenicity and patients should report an increase in severity of intraocular inflammation. Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors. There are limited data on safety in the treatment of DME and macular oedema due to RVO patients with prior history of stroke or transient ischaemic attacks. There is limited experience with treatment of patients with prior episodes of RVO and of patients with ischaemic branch RVO (BRVO) and central RVO (CRVO). In patients with RVO presenting with clinical signs of irreversible ischaemic visual function loss, treatment is not recommended. Lucentis should not be administered concurrently with other anti-VEGF agents (systemic or ocular). Withhold dose and do not resume treatment earlier than the next scheduled treatment in the event of the following: a decrease in BCVA of ≥30 letters compared with the last assessment of visual acuity; an intraocular pressure of ≥30 mmHg; a retinal break; a subretinal haemorrhage involving the centre of the fovea, or if the size of the haemorrhage is ≥50% of the total lesion area; performed or planned intraocular surgery within the previous or next 28 days. Risk factors associated with the development of a retinal pigment epithelial tear after anti-VEGF therapy for wet AMD, include a large and/or high pigment epithelial retinal detachment. When initiating Lucentis therapy, caution should be used in patients with these risk factors for retinal pigment epithelial tears. Discontinue treatment in cases of rhegmatogenous retinal detachment or stage 3 or 4 macular holes. Ranibizumab should not be used during pregnancy unless the expected benefit outweighs the potential risk to the foetus. Women of child-bearing potential should use effective contraception during treatment. Breast-feeding is not recommended during treatment. The treatment procedure may induce temporary visual disturbances and patients who experience these signs must not drive or use machines until these disturbances subside. The vial, injection needle, filter needle and syringe are for single use only. Re-use may lead to infection or other illness/injury. All components are sterile. Any component with packaging showing signs of damage or tampering must not be used. The sterility cannot be guaranteed unless the component packaging seal remains intact. After injection, the needle should not be detatched from the syringe. The syringe should be disposed of together with the needle in a sharps disposal container or in accordance with local requirements. **INTERACTIONS:** No formal interaction studies have been performed. Adjunctive use of verteporfin photodynamic therapy (PDT) and Lucentis in an open study showed a low incidence of intraocular inflammation following initial combination treatment. **ADVERSE REACTIONS:** Patients should be informed of symptoms of these potential adverse reactions and instructed to inform their physician if they develop signs such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in their vision, or increased sensitivity to light. Serious adverse events related to the injection procedure included endophthalmitis, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Other serious ocular events included intraocular inflammation and increased intraocular pressure. **Very Common:** Intraocular pressure increased**,** headache**,** vitritis, vitreous detachment, retinal haemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival haemorrhage, eye irritation, foreign body sensation in eyes, lacrimation increased, blepharitis, dry eye, ocular hyperaemia, eye pruritus, arthralgia**,** nasopharyngitis, urinary tract infections**. Common:** Anaemia**,** retinal degeneration, retinal disorder, retinal detachment, retinal tear, detachment of the retinal pigment epithelium, retinal pigment epithelium tear, visual acuity reduced, vitreous haemorrhage, vitreous disorder, uveitis, iritis, iridocyclitis, cataract, cataract subcapsular, posterior capsule opacification, punctate keratitis, corneal abrasion, anterior chamber flare, vision blurred, injection site haemorrhage, eye haemorrhage, conjunctivitis, conjunctivitis allergic, eye discharge, photopsia, photophobia, ocular discomfort, eyelid oedema, eyelid pain, conjunctival hyperaemia, cough, nausea, allergic reactions (rash, urticaria, pruritus, erythema), hypersensitivity, anxiety. **Uncommon:** Blindness, endophthalmitis, hypopyon, hyphaema, keratopathy, iris adhesion, corneal deposits, corneal oedema, corneal striae, injection site pain, injection site irritation, abnormal sensation in eye, eyelid irritation. Please refer to SmPC for full listing of all undesirable effects. **LEGAL CATEGORY:** POM **PACK SIZES:** Lucentis is supplied in packs containing 1 vial. **MARKETING AUTHORISATION HOLDER**: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom **MARKETING AUTHORISATION NUMBER**: EU/1/06/374/001 **Please refer to Summary of Product Characteristics (SmPC) before prescribing.** Full prescribing information is available on request from Novartis Pharma Services Inc., Representative Office Malta, P.O. Box 4, MRS 1000, Marsa, Malta. Tel: +35621222872 2014-MT-LUC-03-Oct-2014

Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system.
Report forms can be downloaded from http://www.medicinesauthority.gov.mt/adrportal and posted to
Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA or sent by e-mail to postlicensing.medicinesauthority@gov.mt

Healthcare professionals may also report any adverse events suspected to be associated with the use of Lucentis to
Novartis Pharma Services Inc. Representative Office Malta by phone on 21222872, or e-mail at drug_safety.malta@novartis.com

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