A brief guide to the management of risks associated with intravitreal injections during LUCENTIS® (Ranibizumab) treatment

Important Safety Information

Lucentis EU RMP V16.2/ FEB 2017

Introduction

This physician leaflet is part of the educational materials regarding the use of ranibizumab and provides information on the method of administration of ranibizumab and on the prevention and management of key injection-related risks associated with intravitreal injections.

Complete information regarding the safety profile of ranibizumab is detailed within the local prescribing information.[1]

Treatment with ranibizumab

Background

- Ranibizumab is a humanized recombinant monoclonal antibody fragment, specifically designed for intravitreal use that binds and inhibits multiple isoforms of biologically active vascular endothelial growth factor A (VEGF-A).[1]

Prevention and management of key injection-related risks associated with ranibizumab intravitreal injection

Intravitreal injections, including those with ranibizumab, have been associated with infectious endophthalmitis, traumatic cataract, intraocular pressure (IOP) increase (see more information below), as well as intraocular inflammation, rhegmatogenous retinal detachment or retinal tear.[1]

Proper aseptic injection techniques must always be used when administering ranibizumab. In addition, patients should be monitored during the week following the injection to permit early treatment if an infection occurs. Patients should be instructed to report any symptoms suggestive of endophthalmitis or any of the above mentioned events without delay.[1]

Although this leaflet focuses on key ocular risks, there is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. The difference in stroke rates may be greater in patients with known risk factors for stroke, including history of prior stroke or transient ischemic attack. These patients should be carefully evaluated as to whether ranibizumab treatment is appropriate.

Infectious endophthalmitis

Characteristics

- Infectious endophthalmitis is a serious ocular condition consisting of inflammation of the vitreous cavity and can potentially lead to blindness.[2, 3]
- Infectious 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.[4]
- Events such as penetrating trauma, surgical procedures and intravitreal injections that disrupt the integrity of the eye globe, can potentially lead to infectious endophthalmitis.[2, 3]
- Infectious endophthalmitis following ranibizumab injection is uncommon; the reported incidence in ranibizumab clinical trials ranges from ≥1/1,000 to <1/100 patients across all indications.[1]

Prevention and management

- Ranibizumab should be prepared for intravitreal injection and administered according to the steps outlined in the local prescribing information[1], summarized on page 8 and 9 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 report any symptoms suggestive of infectious endophthalmitis without delay.[1]
- Appropriate management and treatment of infectious endophthalmitis should be followed according to local clinical practice.

Iatrogenic traumatic cataract

Characteristics

- Traumatic cataract can be caused by trauma to the intraocular lens following either penetrating or non-penetrating ocular trauma.[5]
- Traumatic cataract may lead to loss of vision and may require surgical intervention.[5, 6]

Prevention and management

- To reduce the risk of traumatic cataract, ranibizumab should be prepared for intravitreal injection and administered according to the steps outlined in the local prescribing information[1], summarized on page 8 and 9 of this leaflet:
  - > 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.
- Patients should be instructed to report any symptoms suggestive of iatrogenic traumatic cataract without delay.[1]
- Appropriate management and treatment of traumatic cataract should be followed according to local clinical practice.

Increases in intraocular pressure

Characteristics

- Transient increases in IOP within 60 minutes of injection of ranibizumab are very common; the reported incidence is ≥1/10 patients in ranibizumab 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.[7]
- Post-injection increases in IOP are often asymptomatic and usually resolve quickly (are transient).[7]

Prevention and management

- Ranibizumab should be administered as a single intravitreal injection with an injection volume of 0.05 mL:[1]
  - > 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.[8]

References

1. Novartis Pharma AG. Lucentis® Summary of Product Characteristics. September 2015. **2.** Kernt M, Kampik A. *Clin Ophthalmol.* 2010;4:121-35. **3.** Spadea L. *US Ophthalmic Rev.* 2014;7(2):146-53. **4.** Chen E, *et al. Retina.* 2011;31(8):1525-33. **5.** Shah M, *et al. Indian J Ophthalmol.* 2011;59(3):217-22. **6.** Thylefors B. *Aust N Z J Ophthalmol.* 1992;20(2):95-8. **7.** Abedi G, *et al. Semin Ophthalmol.* 2013;28(3):126-30. **8.** Aiello LP, *et al. Retina.* 2004;24(Suppl 5):S3-19.

Administration of ranibizumab

- Ranibizumab is available as a vial kit or as a vial with filter needle.
- Ranibizumab should be inspected visually for particulate matter and discoloration prior to administration.
- The vial is for single use only. Ranibizumab is not licensed for multidose, further compounding or vial splitting. Use of more than one injection from the vial may 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 a 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.

Preparation of ranibizumab for intravitreal injection

To prepare the vial for intravitreal administration, please adhere to the following instructions: The vial is for single use only. Ranibizumab is not licensed for multidose, 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.

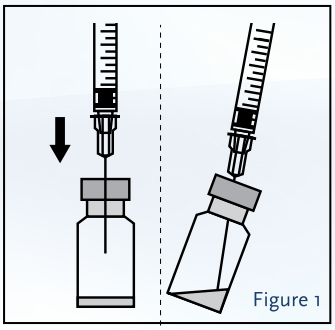


Figure 1

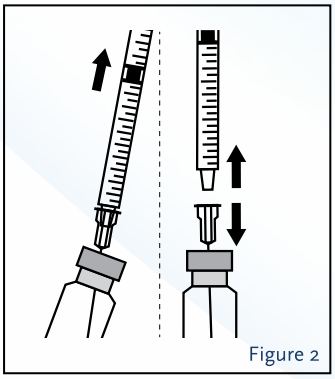


Figure 2

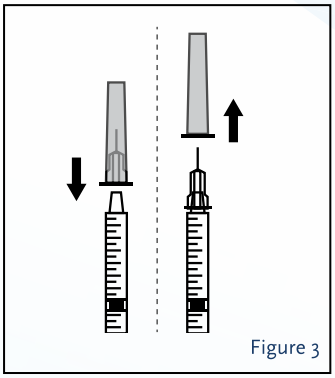


Figure 3

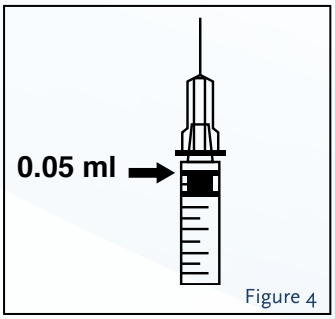


Figure 4

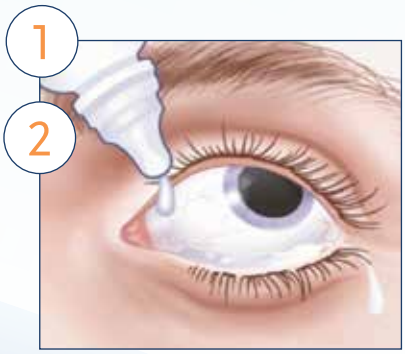
1. Before withdrawal, the outer part of the rubber stopper of the vial should be disinfected.
2. Assemble the 5 µm filter needle (18-gauge) onto the 1 mL syringe using aseptic technique. Push the blunt filter needle into the center of the vial stopper until the needle touches the bottom edge of the vial.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

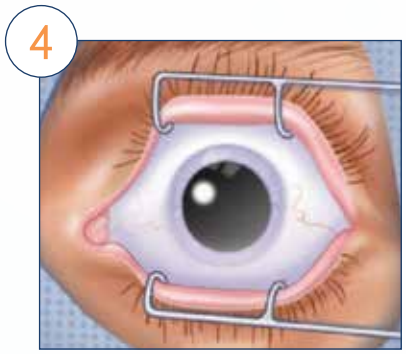
After injection, do not recap the needle or detach it from the syringe. Dispose of the used syringe together with the needle in a sharps disposal container or in accordance with local requirements.

Preparation of the eye and administration of ranibizumab

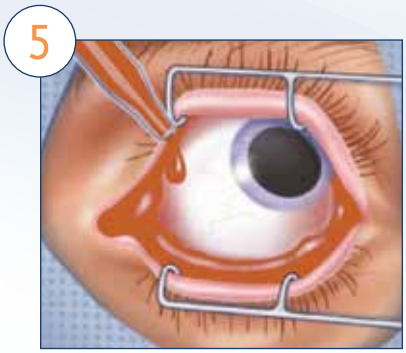


1. Dilate the pupil.
2. Apply topical anesthesia.

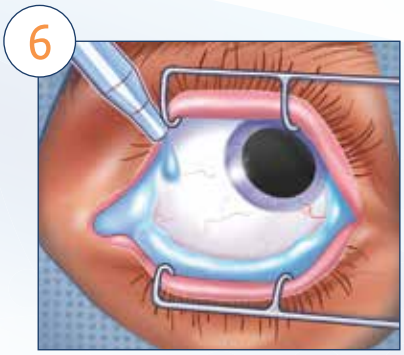
3. Apply 10% povidone iodine solution to periocular skin, lids and eyelashes, and place sterile drape over the eye.



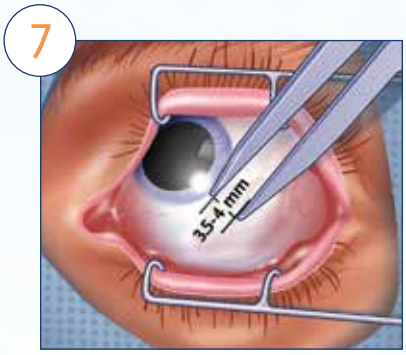
4. Apply sterile eyelid speculum.



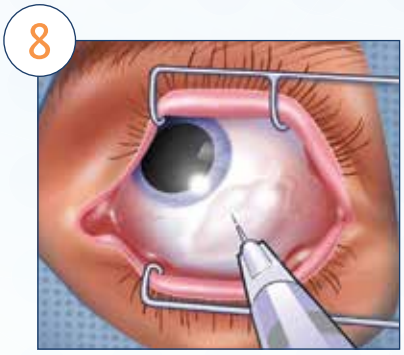
5. Instill 5% povidone iodine ophthalmic solution and wait for 90 seconds.



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 mm to 4.0 mm posterior to the limbus, avoiding the horizontal meridian.



8. The injection needle should be inserted aiming toward the center of the globe. Slowly deliver the injection volume, then remove the needle slowly:
   - A different scleral site should be used for subsequent injections so that the same site is not injected repeatedly.

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

Introduction

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Treatment with ranibizumab

Background

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Prevention and management of key injection-related risks associated with ranibizumab intravitreal injection

Intravitreal injections, including those with ranibizumab, have been associated with infectious endophthalmitis, traumatic cataract, intraocular pressure (IOP) increase (see more information below), as well as intraocular inflammation, rhegmatogenous retinal detachment or retinal tear.[1]

Proper aseptic injection techniques must always be used when administering ranibizumab. In addition, patients should be monitored during the week following the injection to permit early treatment if an infection occurs. Patients should be instructed to report any symptoms suggestive of infectious endophthalmitis or any of the above mentioned events without delay.[1]

Although this leaflet focuses on key ocular risks, there is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. The difference in stroke rates may be greater in patients with known risk factors for stroke, including history of prior stroke or transient ischemic attack. These patients should be carefully evaluated as to whether ranibizumab treatment is appropriate.

Infectious endophthalmitis

Characteristics

- Infectious endophthalmitis is a serious ocular condition consisting of inflammation of the vitreous cavity and can potentially lead to blindness.[2, 3]
- Infectious 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 infectious endophthalmitis occurring after intravitreal injection than after intraocular surgery.[4]
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Prevention and management

- Ranibizumab should be prepared for intravitreal injection and administered according to the steps outlined in the local prescribing information[1], summarized on page 15 to 17 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 report any symptoms suggestive of infectious endophthalmitis without delay.[1]
- Appropriate management and treatment of infectious endophthalmitis should be followed according to local clinical practice.

Iatrogenic traumatic cataract

Characteristics

- Traumatic cataract can be caused by trauma to the intraocular lens following either penetrating or non-penetrating ocular trauma.[5]
- Traumatic cataract may lead to loss of vision and may require surgical intervention.[5, 6]

Prevention and management

- To reduce the risk of iatrogenic traumatic cataract, ranibizumab should be prepared for intravitreal injection and administered according to the steps outlined in the local prescribing inforamtion[1], summarized on page 15 to 17 of this leaflet:
  - > 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.
- Patients should be instructed to report any symptoms suggestive of iatrogenic traumatic cataract without delay.[1]
- Appropriate management and treatment of traumatic cataract should be followed according to local clinical practice.

Increases in intraocular pressure

Characteristics

- Transient increases in IOP within 60 minutes of injection of ranibizumab are very common; the reported incidence is ≥1/10 patients in ranibizumab 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.[7]
- Post-injection increases in IOP are often asymptomatic and usually resolve quickly (are transient).[7]

Prevention and management

- Ranibizumab should be administered as a single intravitreal injection with an injection volume of 0.05 mL:[1]
  - > 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.[8]

References

1. Novartis Pharma AG. Lucentis® Summary of Product Characteristics. September 2015. **2.** Kernt M, Kampik A. *Clin Ophthalmol*. 2010;4:121-35. **3.** Spadea L. *US Ophthalmic Rev*. 2014;7(2):146-53. **4.** Chen E, *et al. Retina*. 2011;31(8):1525-33. **5.** Shah M, *et al. Indian J Ophthalmol*. 2011;59(3):217-22. **6.** Thylefors B. *Aust N Z J Ophthalmol*. 1992;20(2):95-8. **7.** Abedi G, *et al. Semin Ophthalmol*. 2013;28(3):126-30. **8.** Aiello LP, *et al. Retina*. 2004;24(Suppl 5):S3-19.

Administration of ranibizumab

- Ranibizumab is available as a vial kit, vial with filter needle.
- Ranibizumab should be inspected visually for particulate matter and discoloration prior to administration.
- The vial is for single use only. Ranibizumab is not licensed for multidose, further compounding or vial splitting. Use of more than one injection from the vial may 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 a 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.

LUCENTIS®* (ranibizumab) vial and filter needle pack preparation guidelines

**Please refer to the approved LUCENTIS® prescribing information from your country of origin.*

Aseptic technique should be observed during tray assembly, anesthetic preparation, drug preparation and administration. Ranibizumab must be administered by a qualified ophthalmologist experienced in administering intravitreal injections. In addition to the procedures outlined below, intravitreal injection guidelines of your specific clinic should be followed.

Notes

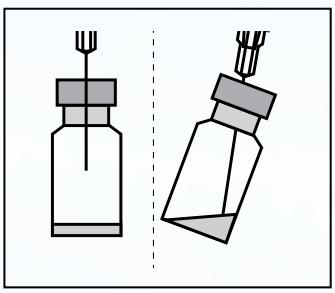
- The vial and filter needle are for single use only
- All components are sterile. Any component with packaging showing signs of damage or tampering must not be used
- The injection procedure should be carried out under aseptic conditions
- **Note: the dose must be set to 0.05 mL**

Before starting

- **Make sure that you have:**
  - > 0.23 mL sterile solution in a vial (type I glass) with a stopper (chlorobutyl rubber) (provided)
  - > 1 blunt filter needle (18 gauge . 1. inch, 1.2 mm . 40 mm, 5 µm) (provided)
  - > 1 injection needle (30 gauge . . inch) (not included)
  - > 1 sterile syringe (1 mL) (not included)

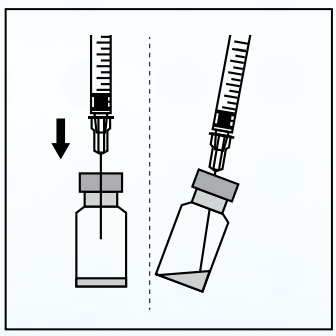
1. Check vial

Only proceed if the vial is not damaged and the drug solution looks clear, colorless to pale yellow and does not contain any particulates, otherwise discard the kit and use a new one. Before withdrawal, the outer part of the rubber stopper of the vial should be disinfected.



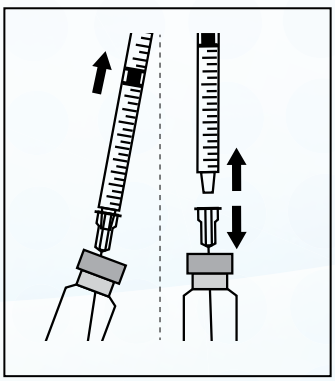
2. Attach filter needle

Attach the 5 µm blunt filter needle (18 gauge . 1. inch, 1.2 mm x 40 mm) 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. Withdraw all the liquid from the vial, keeping the vial in an upright position, slightly inclined to ease complete withdrawal.



3. Withdraw liquid from the vial

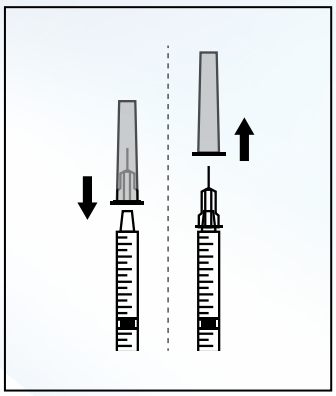
Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle. Leave the blunt filter needle in the vial and disconnect the syringe from the blunt filter needle. The filter needle should be discarded after withdrawal of the vial contents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



4. Attach injection needle

Aseptically and firmly assemble the injection needle (30 gauge . . inch) onto the syringe. Carefully remove the cap from the injection needle without disconnecting the injection needle from the syringe.

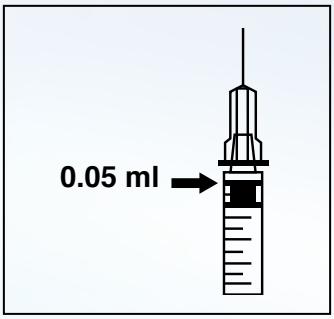
Note: grip at the yellow hub of the injection needle while removing the cap.



5. Set dose

Carefully expel the air from the syringe and adjust the dose to the 0.05 mL mark on the syringe. The syringe is ready for injection.

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



For intravitreal injection guidelines, please see overleaf

LUCENTIS®* (ranibizumab) intravitreal injection guidelines[1]

**Please refer to the approved LUCENTIS® prescribing information from your country of origin.*

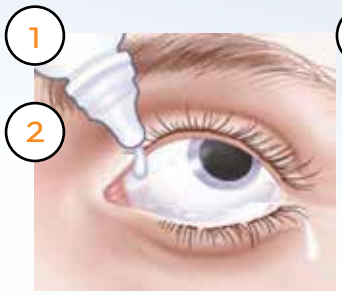
Aseptic technique should be observed during tray assembly, anesthetic preparation, drug preparation and administration. Ranibizumab must be administered by a qualified ophthalmologist experienced in administering intravitreal injections. In addition to the procedures outlined below, intravitreal injection guidelines of your specific clinic should be followed.

Injection supplies

Before starting, aseptically assemble the following supplies:

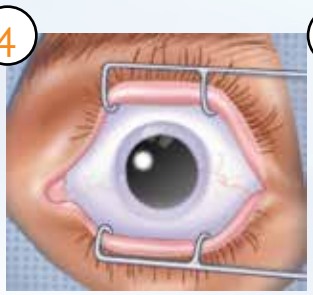
- Sterile surgical gloves
- 4 x 4 sterile pads
- Pupillary dilation agent
- Povidone iodine solution 10%
- Povidone iodine eye drops 5%
- Sterile eyelid speculum
- Sterile ophthalmic drape
- Sterile caliper

Injection procedures

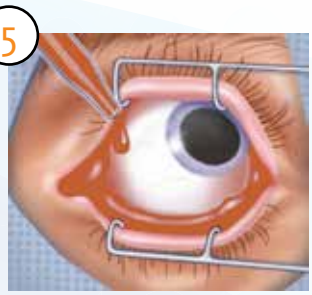


1. Dilate the pupil.
2. Apply topical anesthesia.

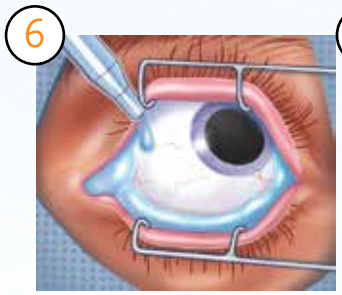
3. Apply 10% povidone iodine solution to periocular skin, lids and eyelashes, and place sterile drape over the eye.



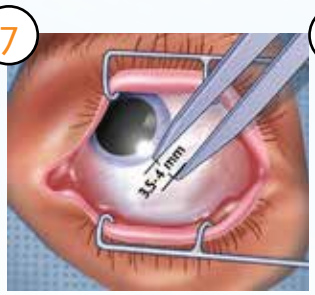
4. Apply sterile eyelid speculum.



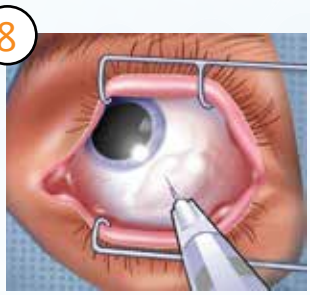
5. Instill 5% povidone iodine ophthalmic solution and wait for 90 seconds.



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 mm to 4.0 mm posterior to the limbus, avoiding the horizontal meridian.



8. The injection needle should be inserted aiming toward the center of the globe. Slowly deliver the injection volume, then remove the needle slowly:
   - A different scleral site should be used 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

Post-injection procedures

- 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
- Evaluate light perception, indirect ophthalmoscope findings, and intraocular pressure immediately post-injection
- Instruct patient to report immediately any signs of inflammation or infection, such as eye pain or discomfort, worsening eye redness, sensitivity to light, vitreous floaters, or vision changes
- Monitor patient during the week following the injection to permit early treatment if an infection occurs

Reference:
1. Aiello LP, *et al. Retina*. 2004;24(Suppl 5):S3-S19.

LUCENTIS® **Note:** Before prescribing, consult full prescribing information. **Presentation: Vial**: Ranibizumab. Each vial contains 2.3 mg of ranibizumab in 0.23 mL solution. **Indications:** ♦Treatment of neovascular (wet) age-related macular degeneration (AMD). ♦Treatment of visual impairment due to diabetic macular edema (DME). ♦Treatment of visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO). ♦Treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM). **Dosage:** ♦The recommended dose is 0.5 mg (0.05 mL) given as a single intravitreal injection. The interval between two doses should not be shorter than 1 month. **AMD, DME RVO:** Patients should be monitored monthly for visual acuity. ♦Treatment is given monthly and continued until maximum visual acuity is achieved, confirmed by stable visual acuity for three consecutive monthly assessments performed while on Lucentis® treatment. Treatment is resumed with monthly injections when monitoring indicates a loss of visual acuity due to wet AMD, DME or macular edema secondary to RVO and continued until stable visual acuity is reached again for three consecutive monthly assessments. ♦Lucentis and laser photocoagulation in DME or in branch RVO: Lucentis has been used concomitantly with laser photocoagulation in clinical studies. 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. **CNV secondary to PM:** Treatment is initiated with a single injection, further treatment is recommended if monitoring reveals signs of disease activity. ♦The frequency of monitoring should be determined by the treating physician. ♦Lucentis must be administered by a qualified ophthalmologist using aseptic techniques. Broad-spectrum topical microbicide and anaesthetic should be administered prior to the injection. ♦Not recommended in children and adolescents. **Contraindications:** Hypersensitivity to ranibizumab or to any of the excipients, patients with active or suspected ocular or periocular infections, patients with active intraocular inflammation. **Warnings/Precautions:** ♦Intravitreous injections have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Therefore proper aseptic injection techniques must be used. Patients should be monitored during the week following the injection to permit early treatment if an infection occurs. ♦Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of injection of Lucentis. Sustained IOP increases have also been reported. Intraocular pressure and the perfusion of the optic nerve head must be monitored and managed appropriately. ♦There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. A numerically higher stroke rate was observed in patients treated with ranibizumab 0.5 mg compared to ranibizumab 0.3 mg or control, however, the differences were not statistically significant. Patients with known risk factors for stroke, including history of prior stroke or transient ischemic attack should be carefully evaluated by their physicians as to whether Lucentis treatment is appropriate and the benefit outweighs the potential risk. ♦Available data do not suggest an increased risk of systemic adverse events with bilateral treatment. ♦As with all therapeutic proteins, there is a potential for immunogenicity with Lucentis. ♦Lucentis has not been studied in patients with active systemic infections or in patients with concurrent eye conditions such as retinal detachment or macular hole. ♦There is limited experience with treatment of patients with prior episodes of RVO and of patients with ischemic branch RVO (BRVO) and central RVO (CRVO). In patients with RVO presenting with clinical signs of irreversible ischemic visual function loss, treatment is not recommended. Should not be used during pregnancy unless the expected benefit outweighs the potential risk to the fetus. 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; use of effective contraception recommended for women of child-bearing potential; breast-feeding not recommended. ♦Following treatment patients may develop transient visual disturbances that may interfere with their ability to drive or use machines. Patients should not drive or use machines as long as these symptoms persist. **Interactions:** No formal interaction studies have been performed. **Adverse reactions: ♦Very common adverse reactions are:** intraocular inflammation, vitritis, vitreous detachment, retinal hemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival hemorrhage, eye irritation, foreign body sensation in eyes, lacrimation increased, blepharitis, dry eye, ocular hyperemia, eye pruritus, intraocular pressure increased, nasopharyngitis, headache, arthralgia. **♦Common adverse reactions are:** retinal degeneration, retinal disorder, retinal detachment, retinal tear, detachment of the retinal pigment epithelium, retinal pigment epithelium tear, visual acuity reduced, vitreous hemorrhage, vitreous disorder, uveitis, iritis, iridocyclitis, cataract, cataract subcapsular, posterior capsule opacification, punctuate keratitis, corneal abrasion, anterior chamber flare, vision blurred, injection site hemorrhage, eye hemorrhage, conjunctivitis, conjunctivitis allergic, eye discharge, photopsia, photophobia, ocular discomfort, eyelid edema, eyelid pain, conjunctival hyperemia, stroke, influenza, urinary tract infection*, anemia, anxiety, cough, nausea, allergic reactions (rash, pruritus, urticaria, erythema). **♦Uncommon adverse reactions are:** blindness, endophthalmitis, hypopyon, hyphema, keratopathy, iris adhesions, corneal deposits, corneal edema, corneal striae, injection site pain, injection site irritation, abnormal sensation in eye, eyelid irritation. **♦Serious adverse events** related to intravitreal injections included endophthalmitis, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract.
**observed only in the DME population*
Packs and prices: Country specific.
Legal classification: Country specific.

Lucentis EU RMP V16/ Feb 2017

NOVARTIS

You can report any problem or adverse events through:
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Fax: +966 11 265 8107
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Saudi Food and Drug Authority National Pharmacovigilance Center
You can report any problem through
Toll free phone: 8002490000
Fax: +966-11-205-7662
E-mail: npc.drug@sfda.gov.sa
Or online: https://ade.sfda.gov.sa

يمكنك الابلاغ عن أي أعراض جانبية أو شكاوى من خلال:
الهيئة العامة للغذاء والدواء المركز الوطني للتيقظ الدوائي
الرقم المجاني: ٨٠٠٢٤٩٠٠٠٠
الفاكس: ٩٦٦١١٢٠٥٧٦٦٢+
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أو شركة نوفارتس
الهاتف: ٩٦٦١١٢٦٥٨١٠٠+
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