LUCENTIS®* pre-filled syringe intravitreal injection guidelines

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

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

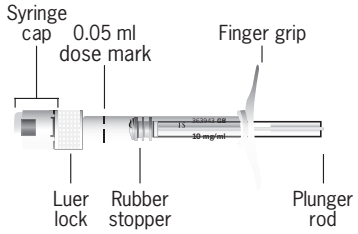
Notes:

- 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**

Before starting:

- Make sure that the pack contains a sterile pre-filled syringe in a sealed tray
- Peel the lid off the syringe tray and, using aseptic technique, carefully remove the syringe

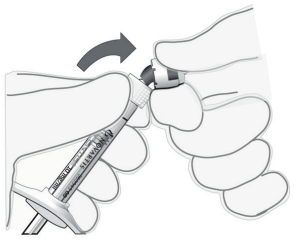
1



Only proceed if the pre-filled syringe cap is not detached from the Luer lock, the syringe is not damaged, and the solution looks clear, colourless to pale yellow and does not contain any particles. Otherwise, discard the pre-filled syringe and use a new one.

Check syringe

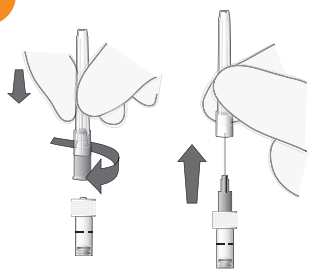
2



Snap off (do not turn or twist) and dispose of the syringe cap.

Remove syringe cap

3



Attach a 30G x ½" sterile injection needle firmly onto the syringe by screwing it tightly onto the Luer lock. Carefully remove needle cap by pulling straight off.

Note: Do not wipe the needle at any time.

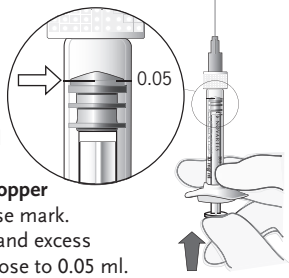
Attach needle

4

Hold syringe upright. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top.

Dislodge air bubbles

5

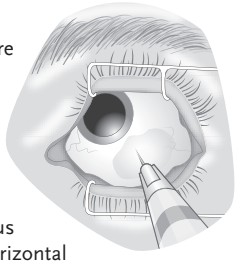


Hold the syringe at eye level and carefully push the plunger until the **edge below the dome of the rubber stopper** is aligned with the dose mark. This will expel the air and excess solution and set the dose to 0.05 ml.

Note: The plunger rod is not attached to the rubber stopper – this is to prevent air being drawn into the syringe.

Set dose

6



The injection procedure should be carried out under aseptic conditions. Insert injection needle 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. Inject slowly until the rubber stopper reaches the bottom of the syringe to deliver the volume of 0.05 ml.

Inject

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
- Instruct patient to report immediately any 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
- A different scleral site should be used for subsequent injections

NOVARTIS PHARMACEUTICALS

LUCENTIS® RANIBIZUMAB
DESIGNED TO SAVE SIGHT

Novartis Pharma AG
CH-4002 Basel, Switzerland

LUC PIC1 08/15 MT

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. **CONTRAINDICATIONS:** 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

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