המידע הבא מיועד לאנשי הצוות הרפואי בלבד: אנא עיינו גם בפרק 3 'כיצד תשתמש בתרופה?'. المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط: يرجى منكم أيضاً قراءة الفقرة 3 "كيفية إستعمال الدواء؟" بتمعن

The following information is intended for medical healthcare professionals only: Please also read section 3 "How should you use the medicine?".

כיצד להכין ולהזריק לוסנטיס كيفية تحضير وحقن لوسينتيس

How to prepare and administer Lucentis

Single-use vial for intravitreal use only.

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

Preterm infants: Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections in preterm infants.

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.

Since the volume contained in the vial (0.23 ml) is greater than the recommended dose (0.05 ml for adults and 0.02 ml for preterm infants), a portion of the volume contained in the vial must be discarded prior to administration.

Use of more than one injection from a vial can lead to product contamination and subsequent ocular infection.

Vial-only pack

The vial is for single use only. After injection, any unused product must be discarded. Any vial showing signs of damage or tampering must not be used. The sterility cannot be guaranteed unless the packaging seal remains intact.

For preparation and intravitreal injection, the following medical devices for single use are needed:

- a 5 µm filter needle (18G)
- a 1 ml sterile syringe (including a 0.05 ml or 0.02 ml mark)
- an injection needle (30G x 1/2").

These medical devices are not included within the Lucentis pack.

Vial + filter needle pack

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.

For preparation and intravitreal injection, the following medical devices for single use are needed:

- a 5 μ m filter needle (18G x 1½", 1.2 mm x 40 mm, provided)
- a 1 ml sterile syringe (including a 0.05 ml or 0.02 ml mark, not included within the Lucentis pack)
- an injection needle (30G x ½"; not included within the Lucentis pack)

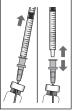
Vial + injection kit

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.

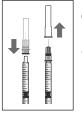
To prepare Lucentis for intravitreal administration, please adhere to the following instructions:



- Before withdrawal, remove the vial cap and clean the vial septum (e.g. with 70% alcohol swab).
- 2. Assemble a 5 µm filter needle (18G x 1½", 1.2 mm x 40 mm, 5 µm) onto a 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.



- 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.



- 6. Aseptically and firmly assemble an injection needle (30G x ½", 0.3 mm x 13 mm) onto the syringe.
- Carefully remove the cap from the injection needle without disconnecting the injection needle from the syringe.
 Note: Grip at the hub of the injection needle while removing the cap.



Carefully expel the air along with the excess solution from the syringe and adjust the dose to the appropriate mark on the syringe. The dose for adults is 0.05 ml. The dose for preterm infants is 0.02 ml. The syringe is ready for injection. Note: Do not wipe the injection needle. Do not pull back on the plunger.

Adults: 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.

Preterm infants: The injection needle should be inserted 1.0 to 2.0 mm posterior to the limbus, with the needle pointing towards the optic nerve. The injection volume of 0.02 ml is then delivered.

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.