NOVARTIS

LUCENTIS®

Pre-filled syringe video

April 2016

AUDIO	TIME	VIDEO
LUCENTIS® is only to be used in accordance with approved prescribing information. Please refer to the approved LUCENTIS® prescribing information from your country of origin.	00:00:00	**Text: LUCENTIS® is only to be used in accordance with approved prescribing information.** **Please refer to the approved LUCENTIS® prescribing information from your country of origin.** **GLO/LUC/0072g(1)**
Because LUCENTIS® is administered by intravitreal injection, proper injection procedures must be followed during the preparation, injection, and post-injection procedures to optimize patient outcomes.	00:00:12	Wide shot of physician in OR injecting patient. This shot is wide enough so as not to be able to clearly see syringe.
Aseptic technique should be observed during injection tray assembly, anesthetic preparation, and LUCENTIS® preparation and administration. Additionally, intravitreal injection guidelines, as outlined in the LUCENTIS® country prescribing information, should be followed.	00:00:25	Nurse putting on gloves, gown and mask. Screen switches to show the tray.
LUCENTIS® is now available in a pre-filled syringe, in addition to vials. The pre-filled syringe comes in a pack that contains a sterile glass syringe in a sealed blister and patient information that includes instructions for use. The pre-filled syringe is only to be used for a single injection.	00:00:42	Close-up of hand opening pre-filled syringe package from the box and removing paper cover. Close-up of packaging on a table. **Text: The pre-filled syringe is for single use only.** **Text: The pre-filled syringe is only to be used for a single patient.**
Carefully read the instructions prior to administering LUCENTIS®. Inspect the cap on the syringe to make sure it is intact and that there is no damage. The syringe cap should not be	00:01:02	Close-up of package leaflet (text is legible). Video showing the syringe being inspected. **Text: Do not use the pre-filled syringe if any part of the packaging is damaged or if the solution is discoloured, cloudy or**

detached from the Luer Lock. Check that the solution looks clear, colorless to pale yellow, and that it does not contain any particles. If any part of the pre-filled syringe is damaged or if the solution appears discolored, cloudy or contains particles, it should be discarded and a new pre-filled syringe used for the procedure.		**contains particles.**
The pre-filled syringe is different from the typical syringe used for injection. Let's take a closer look at the parts that make up this syringe. There is • A plunger rod • A finger grip • A rubber stopper • A 0.05 mL dose mark • A Luer Lock system • And a syringe cap	00:01:36	Highlight parts of the syringe and add text to each. • Plunger Rod • Finger Grip • Rubber Stopper • 0.05 mL Dose Mark • Luer Lock System • Syringe Cap
To prepare the syringe for use, first snap off and dispose of the syringe cap.	00:01:56	Close-up of hands breaking syringe cap.
Attach a 30-gauge sterile injection needle firmly onto the syringe by screwing it tightly onto the Luer Lock system.	00:02:02	Close-up of needle being attached to Luer Lock system. **Text: Attach a 30G x ½" injection needle.**
Carefully remove the needle cap by pulling it straight off. You should never wipe the exposed needle at any time.	00:02:09	Close-up of needle cap being pulled straight off. **Text: Do not wipe the needle at any time.**
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.	00:02:17	Close-up of syringe, and removal of excess solution from the syringe. **Text: The extractable volume of the prefilled syringe (0.1 mL) is not to be used in total.**

To prepare the syringe for injection, hold it upright and check for air bubbles. Gently tap the syringe with your finger until the bubbles rise to the top.	00:02:37	Nurse holds syringe at eye level – taps syringe to dislodge air bubbles.
To expel the air bubble along with the excess solution, 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 black dose mark on the syringe. This sets the dose at 0.05 mL. You should note that the plunger rod is not attached to the rubber stopper. This is to prevent air from being drawn into the syringe. The syringe is now ready for injection.	00:02:46	Extreme close-up with highlight to indicate the edge below the dome of the stopper and the dose mark. **Text with arrow: Dose mark** **Text with arrow: Align the edge <u>below</u> the dome of the stopper with the dose mark.** **Text: The dose must be set to 0.05 ml (i.e., 0.5 mg ranibizumab).** Show that the plunger rod is not attached by letting it drop or pulling it back.
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 if required, the availability of sterile paracentesis. The patient's medical history for hypersensitivity reactions should be carefully evaluated prior to performing the intravitreal procedure.	00:03:15	**Text: The injection procedure should be carried out under aseptic conditions.** Hands showing the apparatus, and then a doctor checking patient records.
The periocular skin, eyelid, and ocular surface should be disinfected, and 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. Dispose of the used syringe together with the needle in a sharps disposal container or in accordance with local requirements. We trust that you have found this video useful for learning the proper procedures for preparing the LUCENTIS® pre-filled syringe. It should be a valuable tool to	00:03:42	Close-up of a patient's face, with povidone iodine being applied to eye area, eye drops applied. OR after the injection.

minimize the potential injection-related adverse events.		
	00:04:24	Novartis logo (with 'Pharmaceuticals' tagline) fades in Novartis Pharma AG CH-4002 Basel Switzerland © 2015 Novartis Pharma AG June 2015 GLO/LUC/0072g(1) (Fade to black)

Suspected adverse reactions and medication errors associated with the use of Lucentis should be reported to: Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, or at: www.medicinesauthority.gov.mt/adrportal

Alternatively at: Novartis Pharma Services Inc. Representative Office Malta by phone on 21222872