

Direct Healthcare Professional Communication (DHPC)

28-Aug-2019

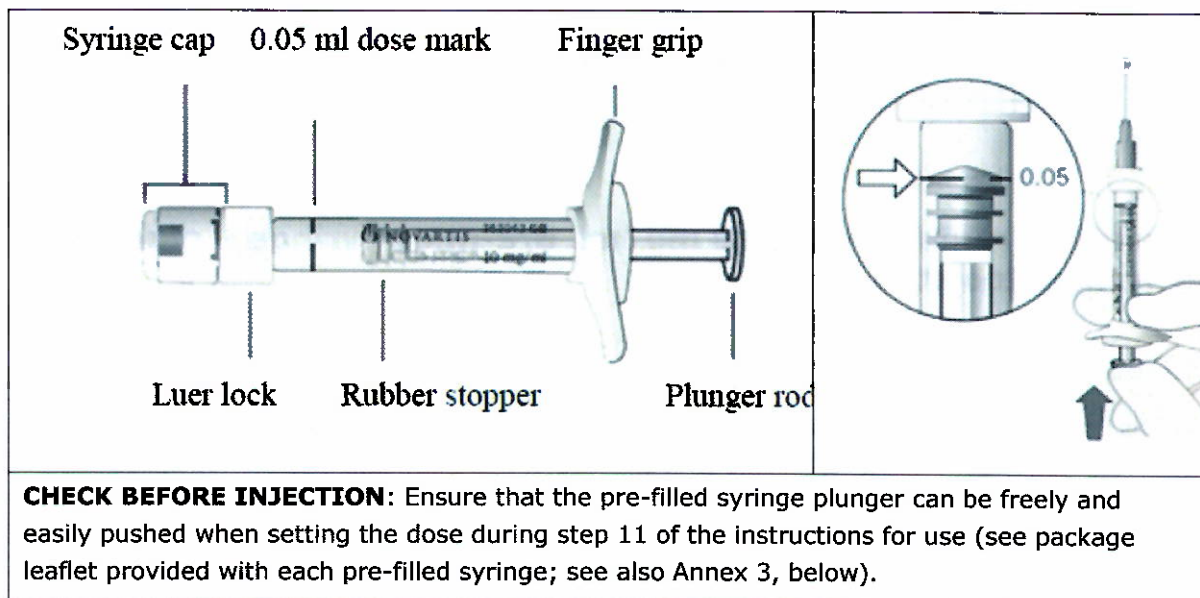
Lucentis® (ranibizumab) 10 mg/mL pre-filled syringe – plunger on syringe too stiff

Dear Healthcare Professional,

Novartis Europharm Ltd. in agreement with the European Medicines Agency and the Health Products Regulatory Authority would like to inform you of the following:

Summary

- **Difficulties have been reported with the plunger of some Lucentis pre-filled syringes, which may result in reduced doses of Lucentis being injected into the patient's eye.**
- **Always check that the pre-filled syringe plunger can be pushed easily when setting the dose (see figure below).**
- **Do not start to inject if the plunger cannot be pushed easily. Use a new pre-filled syringe instead.**
- **Stop the injection if it has already started and the plunger cannot be pushed easily.**
- **If the injection into the patient's eye is incomplete (i.e. less than the recommended 0.05 ml dose has been injected), the medicine's efficacy may be reduced. Monitor treatment efficacy according to current practice.**
- **Follow the recommendation on treatment interval for Lucentis injection, taking into account a minimal interval of 4 weeks between consecutive injections in the same eye as described in Section 4.2 'Posology and method of administration' in the summary of product characteristics (SmPC, see Annex 2 of this letter for excerpt).**
- **Only consider re-injection during the same session if it is imperative for an individual patient, and after you have considered the possibility of excessive dosage (see Section 4.9 'Overdose' in the SmPC in Annex 2 of this letter). Always use a new pre-filled syringe for re-injection.**
- **Return any syringe which does not appear to operate properly to Novartis for evaluation and for notification of potential defect (see Annex 1 below for instructions).**



Background information

Novartis has received complaints from physicians in some countries of difficulties with a stiff plunger in Lucentis pre-filled syringes. The complaints relate to a very small number of syringes from a limited number of batches and an internal investigation is ongoing. Release-testing data from these batches of syringes have been reviewed and we have confirmed that the batches conformed to the specifications for manufacture.

If the Lucentis pre-filled syringe plunger does not move freely, the syringe should not be used. If the injection has already started, it should be stopped. When an injection has been stopped and if re-injection at the same session (using a new pre-filled syringe) is imperative, it is important to consider the possibility of excessive dosage (see summary of product characteristics, section 4.8 on adverse effects and 4.9 on overdosage).

Lucentis is indicated in adults for:

- the treatment of neovascular (wet) age-related macular degeneration (AMD)
- the treatment of visual impairment due to choroidal neovascularization (CNV)
- the treatment of visual impairment due to diabetic macular edema (DME)
- the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO)

Call for reporting

You are reminded to report adverse reactions to Lucentis or product quality complaints with the pre-filled syringe in accordance with the national spontaneous reporting system, as applicable. Healthcare professionals are asked to report any suspected adverse reactions via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517;

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to Novartis Ireland by calling 01-2080 612 or by email to drugsafety.dublin@novartis.com.

Company contact point

Should you have any questions or concerns, please contact Novartis medical information department.

Email: medinfo.dublin@novartis.com

Telephone: 01 2601255

Yours sincerely,



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ANNEX 1: Replacement directions

Please contact Novartis Medical Information to report any syringe which does not appear to operate properly, in order to arrange collection and evaluation. Novartis Medical Information can be contacted using the following contact details:

Email: medinfo.dublin@novartis.com

Telephone: 01 2601255

ANNEX 2: Lucentis summary of product characteristics

**Full SmPC for Lucentis is available from www.medicines.ie
or from EMA website**

<https://www.ema.europa.eu/en/medicines/human/EPAR/lucentis#product-information-section>

ANNEX 3: Instructions for use
See below for an excerpt from SmPC

Lucentis summary of product characteristics (SmPC)

4.2 Posology and method of administration (excerpt only, see SmPC for full information)

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

Posology

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.

Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein angiography).

Lucentis and verteporfin photodynamic therapy in CNV secondary to PM

There is no experience of concomitant administration of Lucentis and verteporfin.

Method of administration

Single-use vial for intravitreal use only.

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

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 (see section 4.4). 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 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 centre of the globe. The injection volume of 0.05 ml is then delivered; a different scleral site should be used for subsequent injections.

4.9 Overdose

Cases of accidental overdose have been reported from the clinical studies in wet AMD and post-marketing data. Adverse reactions associated with these reported cases were intraocular pressure increased, transient blindness, reduced visual acuity, corneal oedema, corneal pain, and eye pain. If an overdose occurs, intraocular pressure should be monitored and treated, if deemed necessary by the attending physician.

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