

המידע הבא מיועד לאנשי הצוות הרפואי בלבד:
المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط:

The following information is intended for healthcare professionals only:

Instruction for use of the pre-filled syringe

Storage and inspection



Store Beovu in the refrigerator (2°C - 8°C). Do not freeze. Keep the pre-filled syringe in its sealed blister and the outer carton in order to protect from light.



Prior to use, the unopened blister with the pre-filled syringe of Beovu may be kept at room temperature (below 25°C) for up to 24 hours. Make sure that your pack contains a sterile pre-filled syringe in a sealed blister. After opening the blister pack, proceed under aseptic conditions.



Beovu is a clear to slightly opalescent and colorless to slightly brownish-yellow aqueous solution.



The solution should be inspected visually upon removal from the refrigerator and prior to administration. If particulates or cloudiness are visible, the pre-filled syringe must not be used and appropriate replacement procedures followed. The pre-filled syringe is sterile and for single use only. Do not use if the packaging or pre-filled syringe are damaged or expired.

How to prepare and administer Beovu

The pre-filled syringe contains more than the recommended dose of 6 mg. The extractable volume of the pre-filled syringe (0.165 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.

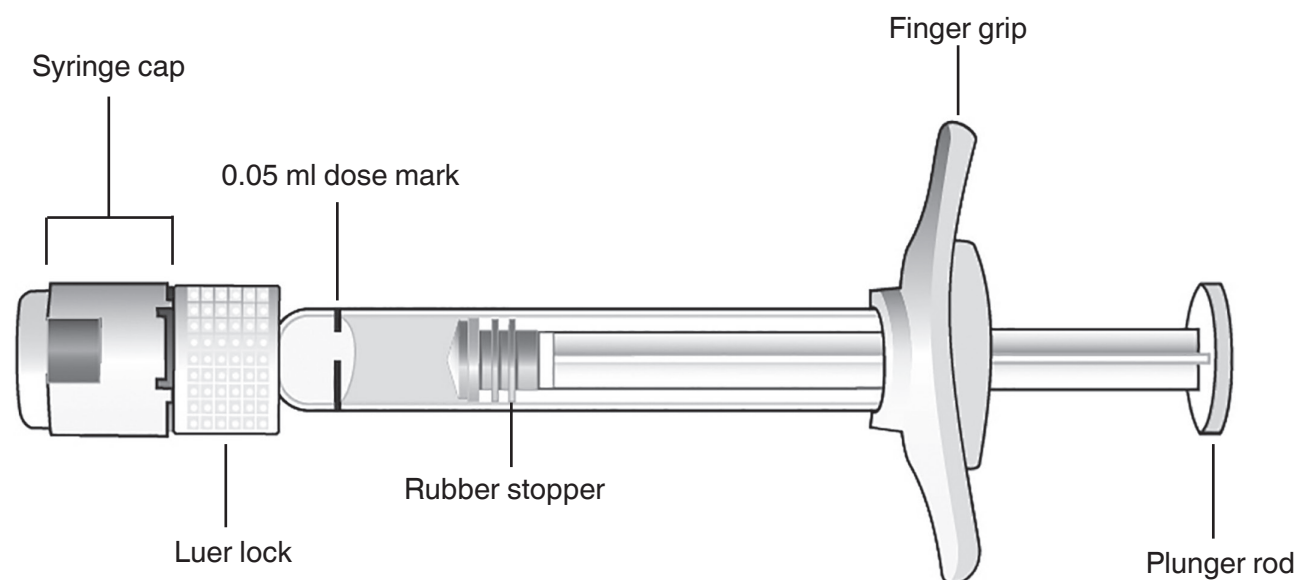
The intravitreal injection procedure must be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape, a sterile eyelid speculum (or equivalent) and the availability of sterile paracentesis equipment (if required).

Adequate anesthesia and a broad-spectrum topical microbicide to disinfect the periorcular skin, eyelid and ocular surface should be administered prior to the injection.

For intravitreal injection, use a 30G x 1/2" sterile injection needle. The injection needle is not included in the Beovu pack.

Ensure that the injection is given immediately after preparation of the dose (step 5).

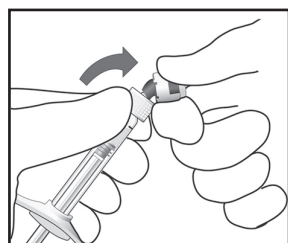
Note: The dose must be set to 0.05 ml.



Injection procedure

- 1 Peel the lid off the syringe blister and, using aseptic technique, remove the syringe.

2

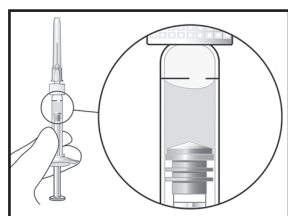


Snap off (do not turn or twist) the syringe cap.

3

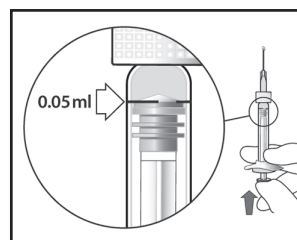
Aseptically and **firmly assemble a 30G x 1/2" injection needle** onto the syringe.

4



To check for air bubbles, hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top. Carefully remove the needle cap by pulling it straight off.

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 **0.05 ml** dose mark. This will expel the air and the excess solution and set the dose to 0.05 ml. The syringe is ready for the injection.

6

Inject slowly until the rubber stopper reaches the end of the syringe in order to deliver a volume of 0.05 ml. **Confirm delivery of the full dose** by checking that the rubber stopper has reached the end of the syringe barrel.

Note: Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Commonly asked questions and answers

Q: What if I cannot remove all the air bubbles from the liquid?

A: It is important for the liquid to be air-free. However, tiny air bubbles that are attached to the stopper usually do not detach from the stopper during the injection and therefore do not affect the dose volume.