Package leaflet: Information for the patient

Byooviz 10 mg/ml solution for injection in pre-filled syringe
ranibizumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Byooviz is and what it is used for

What Byooviz is
Byooviz is a solution which is injected into the eye. Byooviz belongs to a group of medicines called antineovascularisation agents. It contains the active substance called ranibizumab.

What Byooviz is used for
Byooviz is used in adults to treat several eye diseases causing vision impairment.

These diseases result from damage to the retina (light-sensitive layer at the back of the eye) caused by:
- Growth of leaky, abnormal blood vessels. This is observed in diseases such as age-related macular degeneration (AMD) and proliferative diabetic retinopathy (PDR, a disease caused by diabetes). It may also be associated with choroidal neovascularisation (CNV) due to pathologic myopia (PM), angioid streaks, central serous chorioretinopathy or inflammatory CNV.
- Macular oedema (swelling of the centre of the retina). This swelling can be caused by diabetes (a disease called diabetic macular oedema (DME)) or by the blockage of retinal veins of the retina (a disease called retinal vein occlusion (RVO)).

How Byooviz works
Byooviz specifically recognises and binds to a protein called human vascular endothelial growth factor A (VEGF-A) present in the eye. In excess, VEGF-A causes abnormal blood vessel growth and swelling in the eye which can lead to impairment of vision in diseases like AMD, DME, PDR, RVO, PM and CNV. By binding to VEGF-A, Byooviz can block its actions and prevent this abnormal growth and swelling.

In these diseases, Byooviz can help to stabilise and in many cases improve your vision.

2. What you need to know before you are given Byooviz

You must not receive Byooviz
- If you are allergic to ranibizumab or any of the other ingredients of this medicine (listed in section 6).
- If you have an infection in or around your eye.
- If you have pain or redness (severe intraocular inflammation) in your eye.

Warnings and precautions
Talk to your doctor before you are given Byooviz.
- Byooviz is given as an injection into the eye. Occasionally, an infection in the internal portion of the eye, pain or redness (inflammation), detachment or tear of one of the layers in the back of the eye (retinal detachment or tear and retinal pigment epithelial detachment or tear), or clouding of the lens (cataract) may occur after Byooviz treatment. It is important to identify and treat such an infection or retinal detachment as soon as possible. Please tell your doctor immediately if you develop signs such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in your vision or increased sensitivity to light.
- In some patients the eye pressure may increase for a short period directly after the injection. This is something you may not notice, therefore your doctor may monitor this after each injection.
- Inform your doctor if you have a prior history of eye conditions or eye treatments, or if you have had a stroke or experienced transient signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding). This information will be taken into account to evaluate if Byooviz is the appropriate treatment for you.

Please see section 4 ("Possible side effects") for more detailed information on side effects that could occur during Byooviz therapy.

Children and adolescents (below 18 years of age)
The use of Byooviz in children and adolescents has not been established and is therefore not recommended.

Other medicines and Byooviz
Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
- Women who could become pregnant must use effective contraception during treatment and for at least three further months after the last injection of Byooviz.
- There is no experience of using Byooviz in pregnant women. Byooviz should not be used during pregnancy unless the potential benefit outweighs the potential risk to the unborn child. If you are pregnant, think you may be pregnant or planning to become pregnant, discuss this with your doctor before treatment with Byooviz.
- Small amounts of Byooviz may pass into breast milk, therefore Byooviz is not recommended during breast-feeding. Ask your doctor or pharmacist for advice before Byooviz treatment.

Driving and using machines
After Byooviz treatment you may experience some temporary vision blurring. If this happens, do not drive or use machines until this resolves.

3. How Byooviz is given

Byooviz is administered as a single injection into your eye by your eye doctor under a local anaesthetic. The usual dose of an injection is 0.05 ml (which contains 0.5 mg of active substance). The pre-filled syringe contains more than the recommended dose of 0.5 mg. The extractable volume of the pre-filled syringe 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 interval between two doses injected into the same eye should be at least four weeks. All injections will be administered by your eye doctor.

Before the injection, your doctor will wash your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

The treatment is started with one injection of Byooviz per month. Your doctor will monitor the condition of your eye and, depending on how you respond to the treatment, will decide if and when you need to receive further treatment.

Detailed instructions for use are given at the end of the leaflet under "How to prepare and administer Byooviz".

Elderly (age 65 years and over)
Byooviz can be used for people of 65 years of age and over without dose adjustment.

Before stopping Byooviz treatment
If you are considering stopping Byooviz treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Byooviz.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects associated with the administration of Byooviz are either due to the medicine itself or the injection procedure and mostly affect the eye.

The most serious side effects are described below:
Common serious side effects (may affect up to 1 in 10 people): Detachment or tear of the layer in the back of the eye (retinal detachment or tear), resulting in flashes of light with floaters progressing to a temporary loss of sight, or a clouding of the lens (cataract).
Uncommon serious side effects (may affect up to 1 in 100 people): Blindness, infection of the eyeball (endophthalmitis) with inflammation of the inside of the eye.

The symptoms you might experience are pain or increased discomfort in your eye, worsening eye redness, blurred or decreased vision, an increased number of small particles in your vision or increased sensitivity to light. **Please tell your doctor immediately if you develop any of these side effects**.

The most frequently reported side effects are described below:
Very common side effects (may affect more than 1 in 10 people)
Visual side effects include: Inflammation of the eye, bleeding in the back of the eye (retinal bleeding), visual disturbances, eye pain, small particles or spots in your vision (floaters), bloodshot eye, eye irritation, a feeling of having something in the eye, increased tear production, inflammation or infection of the eyelid margins, dry eye, redness or itching of the eye and increased eye pressure.
Non-visual side effects include: Sore throat, nasal congestion, runny nose, headache and joint pain.

Other side effects which may occur following Byooviz treatment are described below:
Common side effects
Visual side effects include: Decreased sharpness of vision, swelling of a section of the eye (uvea, cornea), inflammation of the cornea (front part of eye), small marks on the surface of the eye, blurred vision, bleeding at the site of injection, bleeding in the eye, discharge from the eye with itching, redness and swelling (conjunctivitis), light sensitivity, eye discomfort, swelling of the eyelid, eyelid pain.
Non-visual side effects include: Urinary tract infection, low red blood cells count (with symptoms such

as tiredness, breathlessness, dizziness, pale skin), anxiety, cough, nausea, allergic reactions like rash, hives, itching and skin reddening.

Uncommon side effects
Visual side effects include: Inflammation and bleeding in the front part of the eye, sac of pus on the eye, changes of the central part of the eye surface, pain or irritation at the site of injection, abnormal sensation in the eye, irritation of the eyelid.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Byooviz

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and pre-filled syringe label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C – 8°C). Do not freeze.
- Prior to use, the sealed tray may be stored at temperatures not exceeding 30°C for up to 1 week.
- Keep the pre-filled syringe in its unopened tray in the carton in order to protect from light.
- Do not use any pack that is damaged.

6. Contents of the pack and other information

What Byooviz contains
- The active substance is ranibizumab. Each ml contains 10 mg ranibizumab. One pre-filled syringe contains 0.165 ml, equivalent to 1.65 mg ranibizumab. This provides a usable amount to deliver a single dose of 0.05 ml containing 0.5 mg ranibizumab.
- The other ingredients are α,α-trehalose dihydrate; histidine hydrochloride, monohydrate; histidine; polysorbate 20; water for injections.

What Byooviz looks like and contents of the pack
Byooviz is a solution for injection in a pre-filled syringe. The pre-filled syringe contains 0.165 ml of a sterile, clear, colourless to pale yellow aqueous solution. The pre-filled syringe contains more than the recommended dose of 0.5 mg. The extractable volume of the pre-filled syringe 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.

Pack size of one pre-filled syringe, packed in a sealed tray. The pre-filled syringe is for single use only.

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Other sources of information
To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:
Product Name: Byooviz 10 mg/ml solution for injection in pre-filled syringe
Product Code: PL 45613/0040.
This is a service provided by the Royal National Institute of Blind People (RNIB).

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

Please also refer to section 3 “How Byooviz is given”.

How to prepare and administer Byooviz

Single-use pre-filled syringe for intravitreal use only.

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

In wet AMD, in CNV, in PDR and in visual impairment due to DME or to macular oedema secondary to RVO the recommended dose for Byooviz 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, PDR 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.

If, in the physician’s opinion, visual and anatomical parameters indicate that the patient is not benefiting from continued treatment, Byooviz should be discontinued.

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

If patients are being treated according to a treat-and-extend regimen, once maximum visual acuity is achieved and/or there are no signs of disease activity, the treatment intervals can be extended stepwise until signs of disease activity or visual impairment recur. The treatment interval should be extended by no more than two weeks at a time for wet AMD and may be extended by up to one month at a time for DME. For PDR and RVO, treatment intervals may also be gradually extended, however there are insufficient data to conclude on the length of these intervals. If disease activity recurs, the treatment interval should be shortened accordingly.

The treatment of visual impairment due to CNV should be determined individually per patient based on disease activity. Some patients may only need one injection during the first 12 months; others may need more frequent treatment, including a monthly injection. For CNV secondary to pathologic myopia (PM), many patients may only need one or two injections during the first year.

Ranibizumab and laser photocoagulation in DME and macular oedema secondary to BRVO
There is some experience of ranibizumab administered concomitantly with laser photocoagulation. When given on the same day, ranibizumab should be administered at least 30 minutes after laser photocoagulation. Ranibizumab can be administered in patients who have received previous laser photocoagulation.

Ranibizumab and verteporfin photodynamic therapy in CNV secondary to PM
There is no experience of concomitant administration of ranibizumab and verteporfin.

Byooviz should be inspected visually for particulate matter and discolouration prior to administration.

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.

The pre-filled syringe is sterile and is for single use only. **Do not** use the product if the packaging is damaged or has been tampered with.

To prepare Byooviz for intravitreal administration, please adhere to the instructions for use. Read all the instructions carefully before using the pre-filled syringe.

The opening of the sealed tray and all subsequent steps should be done 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).

For the intravitreal injection, a 30-gauge x ½ inch sterile injection needle should be used (not provided).

Note: The 30-gauge x ½ inch sterile injection needle is not included in the package.

Note: The dose must be set to 0.05 ml.

Device description

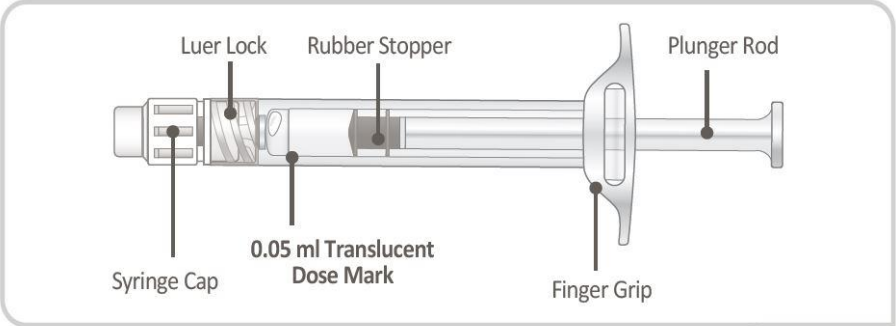
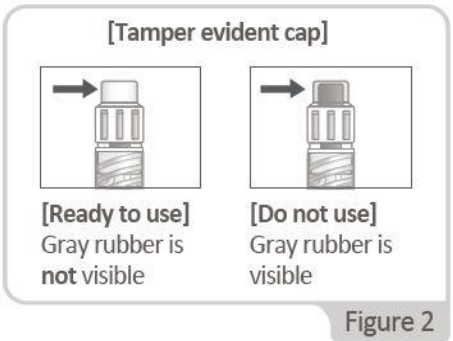
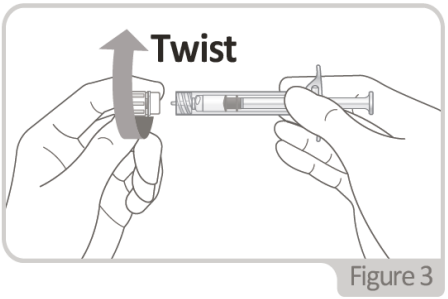
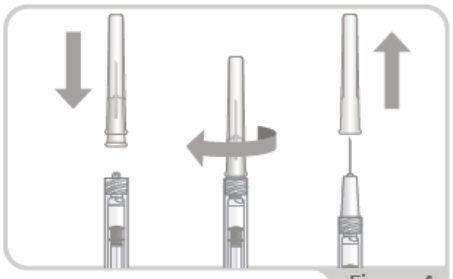
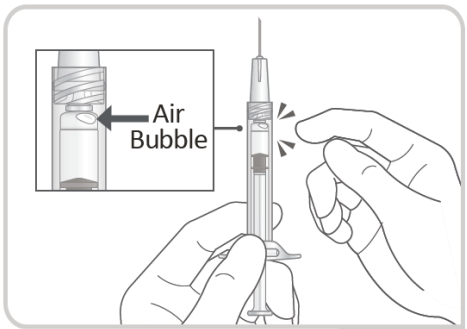
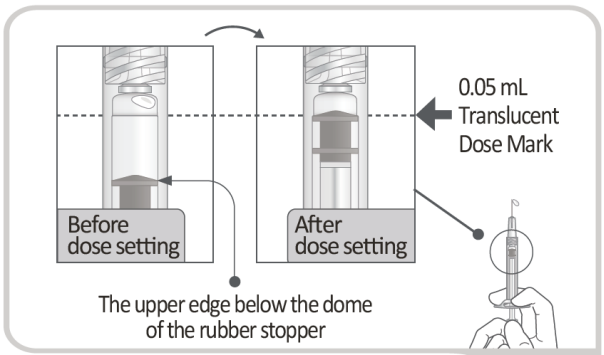


Figure 1

The pre-filled syringe contains more than the recommended dose of 0.5 mg. The excess volume should be expelled prior to injection.

Step 1: Prepare	• Make sure that your pack contains a sterile pre-filled syringe in a sealed tray. • Keep the syringe in the sterile tray until ready for use. • Peel the lid off the syringe tray and, using aseptic technique, remove the syringe.	
Step 2: Inspect syringe	• Byooviz should be colourless to pale yellow. • **Do not** use the pre-filled syringe if: - particulates, cloudiness, or discolouration are visible. - the syringe is damaged. - the syringe cap is not fully closed. - the gray rubber is visible in the transparent part of the syringe cap when holding the syringe vertically at eye level (see Figure 2), indicating that the syringe has been tampered with. ***Note: The plunger rod is completely or partially attached to the rubber stopper. Do not attempt***	 Figure 2

	to attach the plunger rod to the rubber stopper.	
Step 3: Remove syringe cap	• Twist off (**do not** pull or snap off) the syringe cap by holding the syringe in one hand and the syringe cap with the thumb and forefinger of the other hand (see Figure 3).	 Figure 3
Step 4: Attach needle	• Attach a 30 G x ½ inch sterile injection needle firmly onto the syringe by screwing it tightly onto the Luer lock (see Figure 4). • Carefully remove the needle cap by pulling it straight off, when you are ready to administer Byooviz. ***Note: Do not wipe the needle at any time.***	 Figure 4
Step 5: Dislodge air bubbles	• Hold the syringe upright 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 (see Figure 5). ***Note: Do not pull back on the plunger rod at any time, to avoid compromising the sterility of the product.***	 Figure 5
Step 6: Expel air and adjust drug dose	• Hold the syringe at eye level. • Look closely and locate the **translucent dose mark**. • Carefully push the plunger rod until the **upper edge below the dome** of the rubber stopper is aligned with the 0.05 ml translucent dose mark (see Figure 6). • You **may feel resistance** when the rubber stopper contacts the dose mark. The resistance indicates the correct dosing volume of BYOOVIZ has been reached.	 Figure 6
Step 7: Inject	• The injection procedure should be carried out under aseptic conditions. • Insert the needle into the injection site. • Inject slowly until rubber stopper reaches the bottom of the syringe to deliver the volume of 0.05 ml. • A different scleral site should be used for subsequent injections.	
Step 8: Dispose	***Note: After injection, do not recap the needle or detach it from the syringe. This could lead to a needle stick injury.***	

	• The pre-filled syringe is for single use only. Extraction of multiple doses from a pre-filled syringe may increase the risk of contamination and subsequent infection. • Dispose of any unused medicinal product or the used syringe together with the needle in accordance with local requirements or in a sharps disposal container.