

# SUMMARY OF THE RISK MANAGEMENT PLAN

## Summary of risk management plan for Byooviz (ranibizumab)

This is a summary of the risk management plan (RMP) for Byooviz. The RMP details important risks of Byooviz, how these risks can be minimized, and how more information will be obtained about Byooviz's risks and uncertainties (missing information).

Byooviz's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Byooviz should be used.

This summary of the RMP for Byooviz should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Byooviz's RMP.

### I. The medicine and what it is used for

Byooviz is authorized in adults for neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR, visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), and visual impairment due to choroidal neovascularization (CNV). It contains ranibizumab as the active substance. Byooviz is a solution for injection and must be administered by a qualified ophthalmologist experienced in intravitreal injections.

Further information about the evaluation of ranibizumab's benefits can be found in ranibizumab's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

<https://www.ema.europa.eu/en/medicines/human/EPAR/byooviz>

### II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Byooviz, together with measures to minimize such risks and the proposed studies for learning more about Byooviz's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In the case of Byooviz, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Byooviz is not yet available, it is listed under ‘missing information’ below.

## II.A List of important risks and missing information

Important risks of Byooviz are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Byooviz. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

<b>List of important risks and missing information</b>	
Important identified risks	Infectious endophthalmitis Intraocular inflammation Retinal detachment and retinal tear Intraocular pressure increase

## II.B Summary of important risks

<b>Important identified risk: Infectious endophthalmitis</b>	
Evidence for linking the risk to the medicine	Evidence has been derived from information on the reference product (RMP summary and SmPC; information in the public domain) and the conducted Byooviz Phase III study.
Risk factors and risk groups	To minimize the occurrence of endophthalmitis guidance is provided in SmPC on how to administer an intravitreal injection and to inform and educate physicians and patients on prevention and management of this event.  Byooviz is contraindicated in patients with active or suspected ocular or periocular infections or in patients with active severe intraocular inflammation.
Risk minimization measures	<Routine risk minimization measures> SmPC Sections 4.2, 4.3, 4.4, 4.8, 6.6. PL Sections 2, 3, 4. Pack size: One vial for single use only. Restricted medical prescription-only medication  <Additional risk minimization measures>

<b>Important identified risk: Infectious endophthalmitis</b>	
	Educational plan for adult patients

<b>Important identified risk: Intraocular inflammation</b>	
Evidence for linking the risk to the medicine	Evidence has been derived from information on the reference product (RMP summary and SmPC; information in the public domain) and the conducted Byooviz Phase III study.
Risk factors and risk groups	<p>Proper aseptic injection techniques must always be used when administering ranibizumab.</p> <p>Byooviz is contraindicated in patients with active or suspected ocular or periocular infections or in patients with active severe intraocular inflammation.</p>
Risk minimization measures	<p>&lt;Routine risk minimization measures&gt;</p> <p>SmPC Sections 4.3, 4.4.  PL Sections 2, 4.  Pack size: One vial for single use only.  Restricted medical prescription-only medication</p> <p>&lt;Additional risk minimization measures&gt;</p> <p>Educational plan for adult patients</p>

<b>Important identified risk: Retinal detachment and retinal tear</b>	
Evidence for linking the risk to the medicine	Evidence has been derived from information on the reference product (RMP summary and SmPC; information in the public domain) and the conducted Byooviz Phase III study.
Risk factors and risk groups	The following conditions might increase the risk for retinal detachment: previous retinal detachment or retinal tear, eye tumors, inflammation in the choroid or the retina, eye injury, or severe high blood pressure.
Risk minimization measures	<p>&lt;Routine risk minimization measures&gt;</p> <p>SmPC Section 4.4, 4.8.  PL Sections 2, 4.  Pack size: One vial for single use only.  Restricted medical prescription-only medication</p> <p>&lt;Additional risk minimization measures&gt;</p> <p>Educational plan for adult patients</p>

<b>Important identified risk: Intraocular pressure increase</b>	
Evidence for linking the risk to the medicine	Evidence has been derived from information on the reference product (RMP summary and SmPC; information in the public domain) and the conducted Byooviz Phase III study.
Risk factors and risk groups	Pre-existing high IOP; ranibizumab should not be administered in the event of an IOP of $\geq 30$ mmHg.
Risk minimization measures	<p>&lt;Routine risk minimization measures&gt;</p> <p>SmPC Sections 4.4, 4.8, 4.9.  PL Section 2, 4.  Pack size: One vial for single use only.  Restricted medical prescription-only medication</p> <p>&lt;Additional risk minimization measures&gt;</p> <p>Educational plan for adult patients</p>

## **II.C Post-authorization development plan**

### **II.C.1 Studies which are conditions of the marketing authorization**

There are no studies which are conditions of the marketing authorization or specific obligation of Byooviz.

### **II.C.2 Other studies in post-authorization development plan**

There are no studies required for Byooviz.