Swiss Summary of the Risk Management Plan (RMP) for Ranivisio

Version 1.0
Based on EU RMP version 1.0, 08-Jun-2022

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of “Ranivisio” is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of “name of the medicinal product” in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. “Name of the marketing authorisation holder” is fully responsible for the accuracy and correctness of the content of the published summary RMP of “name of the medicinal product”.

The RMP Summary will be checked formally by Swissmedic and, provided there is no cause for complaint, published on the Swissmedic website with a link in www.swissmedicinfo.ch. The marketing authorisation holder will not be informed individually. In the event of a complaint, the marketing authorisation holder will be contacted.

Summary of risk management plan for Ranivisio (ranibizumab)

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

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

This summary of the RMP for Ranivisio 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 Ranivisio's RMP.

I. The medicine and what it is used for

Ranivisio is indicated in adults for the treatment of neovascular (wet) age-related macular degeneration (nAMD), visual impairment due to choroidal neovascularisation (CNV), visual impairment due to diabetic macular oedema (DME), visual impairment due to macular oedema secondary to retinal vein occlusion ([RVO]; branch RVO or central RVO), and proliferative diabetic retinopathy (PDR). It contains ranibizumab as the active substance and it is given by intravitreal injection. It must be administered by a qualified ophthalmologist experienced in intravitreal injections.

Further information about the evaluation of Ranivisio’s benefits can be found in Ranivisio’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/ranivisio.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

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

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised 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 minimise its risks.

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

In the case of Ranivisio, these measures are supplemented with *additional risk minimisation 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 Ranivisio is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ranivisio are risks that need special risk management activities to further investigate or minimise 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 Ranivisio. 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).

List of important risks and missing information	
Important identified risks	• Infectious endophthalmitis • Intraocular inflammation • Retinal detachment and retinal tear • Intraocular pressure increase

II.B Summary of important risks

Important identified risk Infectious endophthalmitis	
Evidence for linking the risk to the medicine	Infectious endophthalmitis can possibly lead to a loss of vision and sometimes even to the loss of the eye itself.
Risk factors and risk groups	Ranibizumab is contraindicated in patients with active or suspected ocular or periocular infections or in patients with active severe intraocular inflammation.
Risk minimisation measures	Routine risk minimisation measures: SmPC Sections 4.2, 4.3, 4.4, 4.8, 6.6. SmPC section 6.6 where advice is given on how to administer an IVT injection and information for physicians and patients on how to manage this event PL Sections 2, 3, 4 Pack size: one single-use vial. Legal status: Prescription only medicine Additional risk minimisation measures: Educational plan for adult patients (for indications of nAMD, CNV, DME, RVO and PDR)

Important identified risk Intraocular inflammation	
Evidence for linking the risk to the medicine	Intraocular inflammation can possibly lead to a loss of vision and sometimes even to the loss of the eye itself.
Risk factors and risk groups	Proper aseptic injection techniques must always be used when administering ranibizumab and injection must not be given to patients with active severe intraocular inflammation.
Risk minimisation measures	Routine risk minimisation: SmPC Sections 4.3, 4.4 PL Sections 2, 4 Pack size limited to one single-use vial. Legal status: Prescription only medicine Additional routine risk minimisation measures: Educational plan for adult patients (for indications of nAMD, CNV, DME, RVO and PDR)

Important identified risk Retinal detachment and retinal tear	
Evidence for linking the risk to the medicine	Retinal detachment leads to visual distortion, and untreated retinal detachment leads to retinal cell death and loss of vision.
Risk factors and risk groups	The following conditions might increase the risk for retinal detachment: previous retinal detachment or retinal tear, eye tumours, inflammation in the choroid or the retina, eye injury, or severe high blood pressure.
Risk minimisation measures	Routine risk minimisation: SmPC Sections 4.4, 4.8 PL Sections 2, 4 Pack size limited to one single-use vial. Legal status: Prescription only medicine Additional routine risk minimisation measures: Educational plan for adult patients (for indications of nAMD, CNV, DME, RVO and PDR)

Important identified risk Intraocular pressure increase	
Evidence for linking the risk to the medicine	The injection of a volume of 50 µL of ranibizumab may lead to an increase in IOP.
Risk factors and risk groups	Pre-existing high IOP is a risk factor. Ranibizumab should not be administered in the event of an IOP of ≥30 mmHg.
Risk minimisation measures	Routine risk minimisation:

	SmPC Sections 4.4, 4.8, 4.9 SmPC Section 4.4 where advice is given on monitoring IOP and the perfusion of the optic nerve head. PL Section 2, 4 Pack size limited to one single-use vial. Legal status: Prescription only medicine Additional risk minimisation measures: Educational plan for adult patients (for indications of nAMD, CNV, DME, RVO and PDR)

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ranivisio.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Ranivisio.