

SUSVIMO®

Injektionslösung in einer Durchstechflasche

39,5mg/0,395ml

Zul.-Nr. 70'522

Public Risk Management Plan (RMP) Summary

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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 "Susvimo" 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 "Susvimo" in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Roche Pharma (Schweiz) AG" is fully responsible for the accuracy and correctness of the content of the published summary RMP of "Susvimo".

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR SUSVIMO[®] (PORT DELIVERY SYSTEM WITH RANIBIZUMAB 100 MG/ML)

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

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

This summary of the RMP for Susvimo should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, all of 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 Susvimo's RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

Susvimo is authorized for use in adult patients for the treatment of neovascular (wet) age-related macular degeneration (see SmPC for the full indication). It contains ranibizumab as the active substance, and recommended dose is 2 mg in 0.02 mL continuously delivered via the ocular implant with refills every 24 weeks (approximately 6 months). Further information about the evaluation of Susvimo's benefits can be found in Susvimo's EPAR, including in its plain-language summary, available on the EMA Web site, under the medicine's Web page.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Susvimo, together with measures to minimize such risks and the proposed studies for learning more about Susvimo'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 package leaflet 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 as 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 Susvimo, these measures are supplemented with additional risk-minimization measures mentioned under relevant risks below.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, including a Periodic Safety Update Report (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 Susvimo is not yet available, it is listed under “missing Information” below.

II.A List of Important Risks and Missing Information

Important risks of Susvimo 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 Susvimo. 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 about 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	PDS implant and PDS procedures complications (vitreous hemorrhage, conjunctival bleb/bleb leak, conjunctival erosion, conjunctival retraction, endophthalmitis, retinal tear and retinal detachment, device dislocation, and traumatic cataract) Septum dislodgement Post-surgical intraocular inflammation
Important potential risks	Implant damage during the PDS procedures (other than septum dislodgement)
Missing information	Long-term safety in post-marketing setting Implant removal-related risks Reimplantation-related risks

PDS = Port Delivery System with ranibizumab.

II.B Summary of Important Risks

Important Identified Risk: PDS implant and PDS procedures complications (vitreous hemorrhage, conjunctival bleb/bleb leak, conjunctival erosion, conjunctival retraction, endophthalmitis, retinal tear and retinal detachment, device dislocation, and traumatic cataract)	
Evidence for linking the risk to the	This identified risk is based on the safety data from Studies

medicine	GX28228, GR40548, and GR40549 in adult patients with nAMD.	
Risk factors and risk groups	The risk factors and risk groups identified for PDS implant and PDS procedures complications are included below. Surgical-related risk factors are based on data available from the PDS clinical development program. Patient related risk factors are presumed based on the potential mechanism of occurrence and the pathophysiology of the complication.	
	Complication	Risk Factors and Risk Groups
	Vitreous hemorrhage	Patients on antithrombotic medication (e.g., oral anticoagulants, aspirin, non-steroidal anti-inflammatory drugs), or patients with coagulation abnormalities, may be at increased risk of vitreous hemorrhage. Vitreous hemorrhage may also occur due to the underlying disease. Surgery-related risk factors include insufficient laser ablation of the pars plana prior to incision, incomplete cauterization of conjunctival and scleral blood vessels around the scleral wound, or improper diathermy of active bleeding within the scleral wound before implant insertion
	Conjunctival bleb/bleb leak (subconjunctival thickening)	No risk group has been identified for the conjunctival bleb/bleb leak complication. Surgery-related risk factors include scleral incision greater than the recommended length in the IFU, as well as excessive suturing leading to long lasting conjunctival inflammation in the area around the implant flange. Refill-exchange-related risk factors include partial needle insertion into the implant, or excessive force applied to the eye while attempting to insert the needle.
	Conjunctival erosion	It is presumed that patients with conjunctival allergies could be at increased risk of conjunctival

		erosions (e.g., due to potential eye rubbing creating tractional forces on the conjunctiva). Patients with thinner conjunctiva might also be at increased risk of conjunctival erosion. Surgery-related risk factors include improper coverage of the implant with Tenon's capsule, or loose-fitting implant due to scleral incision length wider than recommended in the manufacturer's IFU. Conjunctival erosion may also occur due to impaired conjunctival healing after a refill-exchange procedure (i.e., needle track-related erosion)
	Conjunctival retraction	It is presumed that patients with conjunctival allergies could be at increased risk of conjunctival retraction (e.g., due to eye rubbing creating tractional forces on the conjunctiva). Patients with thinner conjunctiva might also be at increased risk of conjunctival retraction. Surgery-related risk factors include insufficient or partial reapposition of the conjunctiva and Tenon's capsule edges with sutures, either at the limbus, or in the radial cut.
	Endophthalmitis	Patients with active or suspected ocular or periocular infections and patients with a severe systemic infection are at risk of endophthalmitis if they undergo PDS procedures. With respect to the implant insertion procedure or refill-exchange procedure, improper aseptic technique is a known risk factor, as well as conjunctival retraction or erosion with implant flange exposure. Furthermore, poor ocular hygiene or failure to use eye protection during high-risk activities

		constitutes additional risk factors for endophthalmitis after the implant insertion procedure.
	Retinal tear and retinal detachment	It is presumed that patients with a thin retina (e.g., secondary to high myopia), peripheral vitreoretinal degenerations (e.g., lattice degeneration), abnormal vitreoretinal adhesions, or posterior vitreous detachment, or any history of rhegmatogenous retinal detachment could be at increased risk of rhegmatogenous retinal detachment, especially after an eye trauma. Surgery-related risk factors include excessive vitreous prolapse or improper management of the vitreous prolapse after pars plana incision or after trocars removal.
	Device dislocation	It is presumed that patients with eye trauma or very high intraocular pressure are at risk of device dislocation. In the clinical development program, most dislocation cases were associated with a longer than recommended incision (>3.7 mm before or after laser ablation of the pars plana) at the time of implantation. Most cases had evidence of “scleral discoloration” around the implant flange on images before the event of dislocation. The “scleral discoloration,” which is seen as darkened areas most often around the outer corners of the implant flange, may demonstrate a transillumination defect and thus may represent an elongated scleral wound. Implant dislocations related to an elongated scleral wound can occur during the refill-exchange procedure as the force from the needle may lead to the movement of

		the implant. Intrinsic and extrinsic risk factors related to the patient could include thin conjunctiva, excessive eye rubbing, and eye trauma.
	Traumatic cataract	No risk group has been identified for the traumatic cataract complications. The event might be linked to the direct trauma to the lens during the procedure
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 Posology and Method of Administration SmPC Section 4.4 Special Warnings and Precautions for Use SmPC Section 4.8 Undesirable Effects PL Section 2 What you need to know before you are given Susvimo PL Section 4 Possible side effects Requirement for strict adherence to the manufacturer's IFU for the initial fill and implant insertion procedure, refill-exchange procedure, and the implant removal procedure is included in Section 4.4 of the SmPC (Special warnings and precautions for use). Warning to temporarily interrupt antithrombotic medication prior to the implant insertion procedure is included in Section 4.4 of the SmPC (Special warnings and precautions for use). Pack size Restricted medical prescription Restriction to perform the PDS implant initial fill and implant insertion, and implant removal procedures by an ophthalmologist experienced in vitreoretinal surgery and trained in the PDS procedures, and restriction to perform the implant refill-exchange procedure by an ophthalmologist trained in the PDS refill-exchange procedures in Section 4.2 of the SmPC. Additional risk minimization measures: Physician Information Pack Patient Educational Materials	
Additional pharmacovigilance	Routine pharmacovigilance activities beyond adverse	

activities	reactions reporting and signal detection: Follow-up questionnaire Additional pharmacovigilance activities: Study GR43341 (Villa) Study GR40549 (Portal) Study GR46011 Note: This study aims to further characterize the following aspects of this important identified risk: endophthalmitis, retinal tear and retinal detachment, which may also be observed with other approved intravitreal medications. See Section II.C of this summary for an overview of the post-authorization development plan.
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IFU = Instructions for Use; nAMD = neovascular age-related macular degeneration; PDS = Port Delivery System with ranibizumab; PL = Patient Leaflet; SmPC = Summary of Product Characteristics.

Important Identified risk: Septum Dislodgement	
Evidence for linking the risk to the medicine	This important identified risk is based on the safety data from Studies GX28228, GR40548, and GR40549 in adult patients with nAMD.
Risk factors and risk groups	Patients implanted with the Phase III implants are at higher risk of experiencing septum dislodgement than those who have received other versions of the implant.
Risk minimization measures	Routine risk minimization measures SmPC Section 4.2 Posology and Method of Administration SmPC Section 4.4 Special Warnings and Precautions for Use SmPC Section 4.8 Undesirable Effects PL Section 2 What you need to know before you are given Susvimo PL Section 4 Possible side effects Requirement for strict adherence to the manufacturer's IFU for the initial fill and implant insertion procedure, refill-exchange procedure, and the implant removal procedure is included in Section 4.4 of the SmPC (Special warnings and precautions for use). Legal status: Restricted medical prescription Section 4.2 of the EU SmPC states: The implant initial fill and implant insertion and implant removal procedures

	must be performed by an ophthalmologist experienced in vitreoretinal surgery and trained in the implant procedures. The implant refill-exchange procedure should be performed by an ophthalmologist trained in the implant refill-exchange procedures. Additional risk minimization measures: Physician Information Pack Patient Educational Materials
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaire Additional pharmacovigilance activities: Study GR43341 (Villa) Study GR40549 (Portal) See Section II.C of this summary for an overview of the post-authorization development plan.

IFU = Instructions for Use; PDS = Port Delivery System with ranibizumab; PL = Patient Leaflet; SmPC = Summary of Product Characteristics.

Important Identified Risk: Post-Surgical Intraocular Inflammation	
Evidence for linking the risk to the medicine	This important identified risk is based on the safety data from Studies GX28228, GR40548, and GR40549 in adult patients with nAMD.
Risk factors and risk groups	Patients with known history of inflammation from uveitis, as well as on chronic treatment with pro-inflammatory drugs (such as prostaglandins) may be more at risk of IOI if they undergo ocular surgeries, including PDS procedures.
Risk minimization measures	Routine risk minimization measures SmPC Section 4.2 Posology and Method of Administration SmPC Section 4.3 Contraindications SmPC Section 4.4 Special Warnings and Precautions for Use SmPC Section 4.8 Undesirable Effects PL Section 2 What you need to know before you are given Susvimo PL Section 4 Possible side effects Pack size Legal status: Restricted medical prescription Section 4.2 of the EU SmPC states: The implant initial fill

	and implant insertion and implant removal procedures must be performed by an ophthalmologist experienced in vitreoretinal surgery and trained in the implant procedures. The implant refill-exchange procedure should be performed by an ophthalmologist trained in the implant refill-exchange procedures. Additional risk minimization measures: Physician Information Pack Patient Educational Materials
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaire Additional pharmacovigilance activities: Study GR40549 (Portal) See Section II.C of this summary for an overview of the post-authorization development plan.

IFU = Instructions for Use; IOI = Intraocular Inflammation; PDS = Port Delivery System with ranibizumab; PL = Patient Leaflet; SmPC = Summary of Product Characteristics.

Important Potential Risk: Implant damage during the PDS procedures (other than Septum Dislodgement)	
Evidence for linking the risk to the medicine	This potential risk is based on the known potential risk associated with any type of medical device.
Risk factors and risk groups	Not yet established
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 Posology and Method of Administration PL Section 2 What you need to know before you are given Susvimo PL Section 4 Possible side effects Strict adherence to the manufacturer's IFU in Section 4.4 of the SmPC (Special warnings and precautions for use). Pack size Restricted medical prescription Restriction to perform the PDS implant initial fill and implant insertion, and implant removal procedures by an ophthalmologist experienced in vitreoretinal surgery and trained in the PDS procedures, and restriction to perform the implant refill-exchange procedure by an ophthalmologist trained in the PDS refill-exchange

	procedures in Section 4.2 of the SmPC. Additional risk minimization measures: Physician Information Pack Patient Educational Materials
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaire Additional pharmacovigilance activities: Study GR40549 (Portal) Study GR43341 (Villa) See Section II.C of this summary for an overview of the post-authorization development plan.

IFU = Instructions for Use; PDS = Port Delivery System with ranibizumab; PL = Patient Leaflet; SmPC = Summary of Product Characteristics.

Missing Information: Long-term Safety in Post-Marketing Setting	
Risk minimization measures	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaire Routine risk minimization measures: None Additional risk minimization measures: None
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaire Additional pharmacovigilance activities: Study GR43341 (Villa) See Section II.C of this summary for an overview of the post-authorization development plan.

Missing Information: Implant Removal-Related Risks	
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 Posology and Method of Administration SmPC Section 4.4 Special Warnings and Precautions for Use PL Section 2 What you need to know before you are given Susvimo Requirement for strict adherence to the manufacturer's IFU for the implant removal procedure is included in Section 4.4 of the

	SmPC (Special Warnings and Precautions). Pack size Restricted medical prescription Restriction to perform the PDS implant initial fill and implant insertion, and implant removal procedures by an ophthalmologist experienced in vitreoretinal surgery and trained in the PDS procedures, and restriction to perform the implant refill-exchange procedure by an ophthalmologist trained in the PDS refill-exchange procedures in Section 4.2 of the SmPC. Additional risk minimization measures: None
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaire Additional pharmacovigilance activities: Study GR43341 (Villa) Study GR40549 (Portal) See Section II.C of this summary for an overview of the post-authorization development plan.

PDS = Port Delivery System with ranibizumab; PL = Patient Leaflet; SmPC = Summary of Product Characteristics.

Missing Information: Reimplantation-related risks	
Risk minimization measures	Routine risk minimization measures: Legal status: Restricted medical prescription Restriction to perform the PDS implant initial fill and implant insertion, and implant removal procedures by an ophthalmologist experienced in vitreoretinal surgery and trained in the PDS procedures, and restriction to perform the implant refill-exchange procedure by an ophthalmologist trained in the PDS refill-exchange procedures in Section 4.2 of the SmPC. Additional risk minimization measures: None
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Follow-up questionnaires

	Additional pharmacovigilance activities: Study GR40549 (Portal) Re-implantation substudy in association with study GR40549 (Portal)
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II.C Post-Authorization Development Plan

II.C.1 Studies That Are Conditions of the Marketing Authorization

There are no studies that are conditions of the marketing authorization or specific obligation of Susvimo.

II.C.2 Other Studies in Post-Authorization Development Plan

Study short name: Study GR43341 (Villa)

Purpose of the study: To evaluate the safety of the implant insertion surgery and the refill-exchange procedure, and the long-term safety and tolerability of the refillable in-dwelling implant in patients implanted with the PDS for treatment of nAMD in clinical practice.

Study short name: Study GR40549 (Portal)

Purpose of the study: To evaluate the long-term safety and tolerability of the PDS (100 mg/mL) in patients with nAMD, including the evaluation of the safety concerns associated with the PDS.

Study short name: Re-implantation substudy in association with study GR40549 (Portal)

Purpose of the study: To evaluate the safety of the reimplantation of PDS implant and the refill-exchange procedures following reimplantation in patients, previously enrolled in the main study, who experienced septum dislodgement while in the main study or after having exited the main study.

Study short name: Study GR46011

Purpose of the study: to compare ranibizumab (administered via the PDS implant) to other approved intravitreal medications by monitoring the following safety outcomes: endophthalmitis, retinal tear and retinal detachment.