Johnson&Johnson

Summary of the Risk Management Plan (RMP) for IMAAVY® (Nipocalimab)

Marketing Authorisation Holder (MAH): Janssen-Cilag AG

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Disclaimer:

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 IMAAVY® 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 IMAAVY® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo-pro.ch) approved and authorized by Swissmedic. Janssen-Cilag AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of IMAAVY®.

Summary of Risk Management Plan for IMAAVY (Nipocalimab)

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

IMAAVY's Company Core Data Sheet (CCDS) and Company Core Patient Information (CCPI) documents give essential information to healthcare professionals on how IMAAVY should be used.

This summary of the RMP for IMAAVY 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 Swiss Public Assessment Report (SwissPAR).

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

1. The Medicine and What it is Used For

IMAAVY is authorized as an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult and adolescent patients aged 12 years and older who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive (see SmPC for the full indication). It contains nipocalimab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of IMAAVY’s benefits can be found in IMAAVY’s SwissPAR, including in its plain-language summary, available on the Swissmedic website.

2. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of IMAAVY, together with measures to minimize such risks and the studies for learning more about IMAAVY'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 CCDS addressed to 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 (eg, with or without prescription) can help to minimize its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed including periodic safety update report 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 IMAAVY is not yet available, it is listed under 'missing information' below.

2.1 List of Important Risks and Missing Information

Important risks of IMAAVY 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 IMAAVY. 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 (eg, on the long-term use of the medicine).

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	Serious hypersensitivity reactions Serious infections
Missing information	Long-term safety of nipocalimab Use during the first trimester of pregnancy

2.2 Routine Risk Minimization Activities by Safety Concern

Safety Concern	**Routine Risk Minimization Activities**
Serious hypersensitivity reactions	**Routine risk communication:** • CCDS Section Warnings and Precautions • CPPI Section 4 **Routine risk minimization activities recommending specific clinical measures to address the risk:** • A recommendation to monitor for signs or symptoms of hypersensitivity reactions is provided in CCDS Section Warnings and Precautions and Section Preparation and Administration Instructions. • Advice on the management of serious hypersensitivity reactions is included in CCDS Section Warnings and Precautions. • Advice for patients to inform their healthcare provider about any previous allergic reaction to nipocalimab or any of the excipients of the formulation before starting nipocalimab is included in CPPI Section 2. • Advice for patients to inform their healthcare provider right away if they experience symptoms of an allergic reaction is included in CPPI Section 4.

	Other routine risk minimization activities beyond the Product Information: • None
Serious infections	**Routine risk communication:** • CCDS Section Warnings and Precautions **Routine risk minimization activities recommending specific clinical measures to address the risk:** • Advice to delay administration of nipocalimab in patients with active infection and a recommendation to monitor patients for clinical signs and symptoms of infection during treatment with nipocalimab are included in CCDS Section Warnings and Precautions. • Advice on the management of serious infections is included in CCDS Section Warnings and Precautions. • Advice for patients to inform their healthcare provider if they are being treated for or have any symptoms of an infection before starting nipocalimab is included in CPPI Section 2. **Other routine risk minimization activities beyond the Product Information:** • None
Long-term safety of nipocalimab	**Routine risk communication:** • None **Routine risk minimization activities recommending specific clinical measures to address the risk:** • None **Other routine risk minimization activities beyond the Product Information:** • None
Use during the first trimester of pregnancy	**Routine risk communication:** • CCDS Section Pregnancy, Breast-feeding and Fertility **Routine risk minimization activities recommending specific clinical measures to address the risk:** • Advice on treating pregnant individuals with nipocalimab is included in CCDS Section Pregnancy, Breast-feeding and Fertility. • Advice for patients to inform their healthcare provider before starting nipocalimab if they are pregnant, think they may be pregnant, or are planning to become pregnant is included in CPPI Section 2. **Other routine risk minimization activities beyond the Product Information:** • None

Additional Risk Minimization Activities:

Not applicable. Routine risk minimization activities as described in Part 2.2 are sufficient to manage the safety concerns of the medicinal product.

2.3 Summary of Risk Minimization Activities and Pharmacovigilance Activities

Safety Concern	Risk Minimization Activities	Pharmacovigilance Activities
Serious hypersensitivity reactions	**Routine risk communication:** • CCDS Section Warnings and Precautions • CPPI Section 4 **Specific clinical measures:** • Recommendation to monitor for signs or symptoms of hypersensitivity reactions: CCDS Section Warnings and Precautions, and Section Preparation and Administration Instructions. • Advice on the management of serious hypersensitivity reactions: CCDS Section Warnings and Precautions. • Advice for patients to inform their healthcare provider about any previous allergic reaction to nipocalimab or any of the excipients of the formulation before starting nipocalimab: CPPI Section 2. • Advice for patients to inform their healthcare provider right away if they experience symptoms of an allergic reaction: CPPI Section 4. **Additional risk minimization activities:** • None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:** • Questionnaire to collect information on hypersensitivity reactions (TOIQ for Hypersensitivity and Anaphylactic Reaction) **Additional pharmacovigilance activities:** • Trial MOM-M281-011 (OLE phase) • Trial 80202135MYG2001 (LTE phase)
Serious infections	**Routine risk communication:** • CCDS Sections Warnings and Precautions **Specific clinical measures:** • Advice to delay administration of nipocalimab in patients with active infection and a recommendation to monitor patients for clinical signs and symptoms of infection during treatment with nipocalimab: CCDS Section Warnings and Precautions. • Advice on the management of serious infections: CCDS Section Warnings and Precautions. • Advice for patients to inform their healthcare provider if they are being	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:** • None **Additional pharmacovigilance activities:** • Trial MOM-M281-011 (OLE phase) • Trial 80202135MYG2001 (LTE phase)

Safety Concern	Risk Minimization Activities	Pharmacovigilance Activities
	treated for or have any symptoms of an infection before starting nipocalimab: CPPI Section 2. **Additional risk minimization activities:** • None	
Long-term safety of nipocalimab	**Routine risk communication:** • None **Specific clinical measures:** • None **Additional risk minimization activities:** • None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:** • None **Additional pharmacovigilance activities:** • Trial MOM-M281-011 (OLE phase) • Trial 80202135MYG2001 (LTE phase)
Use during the first trimester of pregnancy	**Routine risk communication:** • CCDS Section Pregnancy, Breast-feeding and Fertility **Specific clinical measures:** • Advice on treating pregnant individuals with nipocalimab: CCDS Section Pregnancy, Breast-feeding and Fertility. • Advice for patients to inform their healthcare provider before starting nipocalimab if they are pregnant, think they may be pregnant, or are planning to become pregnant: CPPI Section 2. **Additional risk minimization activities:** • None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:** • Questionnaire to collect information on use during pregnancy (Product Exposure During Pregnancy Collection) **Additional pharmacovigilance activities:** • None

3. Postauthorization Development Plan

3.1 Studies That are Conditions of the Marketing Authorization

No studies are conditions of the marketing authorization or specific obligations of IMAAVY.

3.2 Other Studies in Postauthorization Development Plan

1. **OLE of Trial MOM-M281-011**: A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, pharmacokinetics, and

pharmacodynamics of nipocalimab administered to adults with generalized myasthenia gravis.

Purpose of the trial (OLE phase): To evaluate the maintenance of nipocalimab's effect and the long-term safety of nipocalimab in adults with gMG.

2. **LTE of Trial 80202135MYG2001**: An open-label, uncontrolled, multicenter study to evaluate the pharmacokinetics, pharmacodynamics, safety, and activity of nipocalimab in children aged 2 to less than 18 years with generalized myasthenia gravis.

   Purpose of the trial (LTE phase): To evaluate the maintenance of nipocalimab's effect and the long-term safety of nipocalimab in children aged 2 to less than 18 years with gMG.