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Swiss Summary of the Risk Management Plan (RMP) for Mvasi® (bevacizumab biosimilar)

RMP Summary: Version 2, March 2021
EU RMP: Version 2.0, 08 January 2021

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 MVASI® 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 MVASI® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

AMGEN Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of MVASI®.

The medicine and what it is used for

MVASI® is authorized for metastatic carcinoma of the colon or rectum, metastatic breast cancer, advanced metastatic or recurrent non-small cell lung cancer (NSCLC), advanced and/or metastatic renal cell cancer, glioblastoma (WHO grade IV), ovarian cancer, cervical cancer.
It contains bevacizumab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of MVASI®'s benefits can be found in MVASI®'s EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: https://www.ema.europa.eu/medicines/human/EPAR/MVASI.

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

Important risks of MVASI®, together with measures to minimize such risks and the proposed studies for learning more about MVASI®'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 to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the public (eg, with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimization measures.

List of important risks and missing information

Important risks of MVASI 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 MVASI. 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	None
Missing information	None

Summary of Important Risks

Since there are no safety concerns identified in summary of the safety concerns, no summary of important risks is applicable.

Post-authorisation development plan

Studies which are a condition of the marketing authorisation

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

Other studies in postauthorisation development plan

There are no studies required for MVASI®.

Summary of Changes to the Risk Management Plan Over Time

Version	Date of RMP Approval Date Procedure	Change
1.0	30 July 2020 EMEA/H/C/004728/IB/0018	Safety Concerns Important Identified Risks: The following important identified risks were removed: • Bleeding/hemorrhage • Pulmonary hemorrhage • Proteinuria • Arterial thromboembolic events • Hypertension • Congestive heart failure • Wound healing complications • Gastrointestinal perforations • Reversible posterior leukoencephalopathy syndrome • Neutropenia • Venous thromboembolic events • Fistula (other than gastrointestinal) • Thrombotic microangiopathy • Pulmonary hypertension • Ovarian failure • Hypersensitivity reactions/infusion reactions

Version	Date of RMP Approval Date Procedure	Change
1.0 (continued)	30 July 2020 EMEA/H/C/004728/IB/0018	Safety Concerns (continued) Important Identified Risks: The following important identified risks were removed: • Gall bladder perforation • Peripheral sensory neuropathy • Cardiac disorders (excluding congestive heart failure and arterial thromboembolic events) • Osteonecrosis of the jaw • Necrotizing fasciitis • Adverse events following off-label intravitreal use • Embryo-fetal development disturbance • Osteonecrosis in children Missing Information The following missing information was removed • Safety profile of the different treatment combinations in patients with non-squamous non-small cell lung cancer • Long-term effects of MVASI® when used in the pediatric population • Safety and efficacy in patients with renal impairment • Safety and efficacy in patients with hepatic impairment • Use in pregnant and lactating women Pharmacovigilance Plan Specific Adverse Drug Reaction Follow-up Forms were removed: • Arterial thromboembolic event • Congestive heart failure • Anaphylactic reaction • ostenocrosis of the jaw • initial pregnancy – Mother, initial pregnancy – Father, and lactation.

Version	Date of RMP Approval Date Procedure	Change
1.0 (continued)	30 July 2020 EMEA/H/C/004728/IB/0018	Postauthorization Efficacy Plan Not applicable Risk Minimization Measures No change Annexes Annex 4 • Arterial thromboembolic event • Congestive heart failure • Anaphylactic reaction • ostenocrosis of the jaw • initial pregnancy – Mother, initial pregnancy – Father, and lactation Annex 7 References updated
1.1	04 December 2020 Approval date: 21 December 2020 EMEA/H/C/004728/IB/0018	Safety Concerns: No change Pharmacovigilance Plan: Specific Adverse Drug Reaction Follow-up Forms were removed: • Medication error • Interstitial lung disease Postauthorization Efficacy Plan: No change Risk Minimization Measures: No change Annexes Removed from Annex 4: • Medication error • Interstitial lung disease
2.0	08 January 2021 To be confirmed by EMA.	Safety Concerns: No change Pharmacovigilance Plan: No change Postauthorization Efficacy Plan: No change Risk Minimization Measures: No change Annexes: No change Other Changes: Updated indication to include paclitaxel in 'MVASI in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer' to align with the reference medicinal product, Avastin®.