AQUIPTA®

Atogepant

Swiss Summary of the Risk Management Plan (RMP)

Version 1 (27 March 2024)

Based on Core RMP version 1.2 (April 2023)

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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 minimize them. The RMP summary of AQUIPTA® 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 AQUIPTA® in Switzerland is the "Arzneimittelinformation/Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. AbbVie AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of AQUIPTA®.

Part VI: Summary of the Risk Management Plan

Summary of risk management plan for atogepant

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

Atogepant's Summary of Product Characteristics (SmPC) and its Patient Information Leaflet (PIL) give essential information to healthcare professionals and patients on how atogepant should be used.

This summary of the RMP for atogepant 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 are part of the European Public Assessment Report (EPAR).

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

I The Medicine and What it Is Used For

Atogepant is authorized for the prophylaxis of migraine in adults with at least 4 migraine days per month (see SmPC for the full indication). It contains atogepant as the active substance and it is taken by mouth as 10 mg or 60 mg tablets once daily for episodic migraine, or 60 mg once daily for chronic migraine, with or without food.

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

Important risks of atogepant, together with measures to minimize such risks and the proposed studies for learning more about atogepant 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 PIL 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.

No aRMMs are planned or proposed for atogepant. Routine RMMs as described in Part V.1 are sufficient to manage the safety concerns of the medicinal product.

If important information that may affect the safe use of atogepant is not yet available, it is listed under “missing information” below.

II.A List of Important Risks and Missing Information

Important risks of atogepant are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 atogepant. 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	None
Important potential risks	None
Missing information	Use in patients with significant cardiovascular and cerebrovascular diseases Use in pregnant women Long-term safety beyond 1 year

II.B Summary of Important Risks

Missing information Risk 1: Use in patients with significant cardiovascular and cerebrovascular diseases	
Risk minimization measures	Routine risk minimization measures: None proposed.
Additional PV activities	PASS: an observational study to characterize the safety of atogepant in patients with significant cardiovascular and cerebrovascular diseases.

Missing information Risk 2: Use in pregnant women	
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.6.
Additional PV activities	Additional PV activities: Studies P22-419 (PMR 4152-7) and P22-392 (PMR 4152-6)

Missing information Risk 3: Long-term safety beyond 1 year	
Risk minimization measures	Routine risk minimization measures: None proposed.
Additional PV activities	Additional PV activities: Study 3101-312-002

II.C Post-Authorization Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorization

None

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

A Phase 3, multicenter, open-label, 104-week extension study to evaluate the long-term safety and tolerability of oral atogepant for the prevention of migraine in participants with chronic or episodic migraine: Study 3101-312-002

Purpose of the study: To evaluate the long-term safety and tolerability of atogepant 60 mg once daily in participants when taken for 104 weeks for the prevention of chronic or episodic migraine. Study 3101-312-002 will be extended by an additional 1 year for a total of 3 years.

Atogepant pregnancy exposure registry (PMR 4152-6): Study P22-392

Purpose of the study: To prospectively evaluate maternal, fetal, and infant outcomes through 12 months of age among women exposed to atogepant during pregnancy.

Observational study to assess pregnancy outcomes following exposure to atogepant (PMR 4152-7): Study P22-419

Purpose of the study: To describe and compare the incidence of adverse pregnancy outcomes in women with migraine who are exposed to atogepant during pregnancy compared to comparator groups.

PASS of Atogepant in Patients with Significant Cardiovascular and Cerebrovascular Diseases Summary

Purpose of study: To characterize the safety of atogepant in patients with significant cardiovascular and cerebrovascular diseases.