

BRILIQUE™

60 mg and 90 mg film-coated tablets

90 mg orodispersible tablets

Summary of the Risk Management Plan (RMP) for BRILIQUE™® (ticagrelor)

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

SUMMARY OF THE RISK MANAGEMENT PLAN FOR BRILIQUE (TICAGRELOR)

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

Brilique's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Brilique should be used.

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

I: THE MEDICINE AND WHAT IT IS USED FOR

Brilique, co-administered with acetylsalicylic acid (ASA), is authorised for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (ACS) or a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event (see SmPC for the full indication). It contains ticagrelor as the active substance and it is given orally.

Further information about the evaluation of Brilique's benefits can be found in Brilique's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage and in the "Arzneimittelinformation/ Information sur le médicament" under www.swissmedic.ch.

II: RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Brilique, together with measures to minimise such risks and the proposed studies for learning more about Brilique'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 (eg, with or without prescription) can help to minimise its risks.

Together, these measures constitute routine RMM.

II: 1 List of important risks and missing information

Important risks of Brilique are risks that need special risk management activities to further investigate or minimise 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 Brilique. 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	Increased risk of bleeding
Important potential risks	None
Missing information	Long-term use in patients with prior ischaemic stroke

II: 2 Summary of important risks

Important identified risk – Increased risk of bleeding

Evidence for linking the risk to the medicine	Reports from clinical studies, reports from marketed use and medical/scientific literature. Bleeding is considered one of the most commonly reported ADRs in patients treated with ticagrelor. Bleeding constitutes the most important safety issue for all antiplatelet medications.
Risk factors and risk groups	Patients with a propensity to bleed (eg, due to recent trauma, recent surgery, coagulation disorders, active or recent gastrointestinal bleeding). Patients with concomitant administration of medicinal products that may increase the risk of bleeding (eg, NSAIDs, oral anticoagulants and/or fibrinolytics) within 24 hours of ticagrelor dosing.
Risk minimisation measures	Routine risk communication: SmPC sections 4.3, 4.4, 4.8. PL section 2 and 4. Routine risk minimisation activities recommending specific clinical measures to address the risk: Recommendation to use ticagrelor with caution in patients with a propensity to bleed and in patients with concomitant administration of medicinal products that may increase the risk of bleeding (SmPC section 4.4).

II: 3 Post-authorisation development plan

II: 3.1 Studies that are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Brilique.

II: 3.2 Other studies in post-authorisation development plan

None