

Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)

Ticagrelor Medreg 60 mg potahované tablety

Ticagrelor Medreg 90 mg potahované tablety

Administrativní informace:

Léčivá látka/látky	tikagrelor
Léková forma/formy	Potahovaná tableta
Síla/síly	60 mg, 90 mg
Držitel rozhodnutí o registraci	MEDREG s.r.o.
Registrační číslo/čísla	16/427/24-C 16/428/24-C
Verze a datum plánu řízení rizik	1.0, 31.03.2025

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

- 1) [Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů](#)

Summary of risk management plan for Ticagrelor Medreg (ticagrelor)

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

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

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

I. The medicine and what it is used for

Ticagrelor Medreg when co-administered with acetylsalicylic acid (ASA), is indicated 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.

It contains ticagrelor as the active substance, and it is given orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Ticagrelor Medreg, together with measures to minimise such risks and the proposed studies for learning more about Ticagrelor Medreg's, 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 (e.g. with or without a prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, 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 Ticagrelor Medreg is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ticagrelor Medreg 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 Ticagrelor Medreg. 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	Increased risk of bleeding
Important potential risks	None
Missing information	Long-term use in patients with prior ischaemic stroke

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ticagrelor Medreg.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Ticagrelor Medreg.