

## Part VI: Summary of the risk management plan

### Summary of risk management plan for

### “Ticagrelor SUN 60 mg and 90 mg film-coated tablets” (ticagrelor)

This is a summary of the risk management plan (RMP) for Ticagrelor SUN 60 mg and 90 mg film-coated tablets. The RMP details important risks of Ticagrelor SUN 60 mg and 90 mg film-coated tablets and how more information will be obtained about Ticagrelor SUN 60 mg and 90 mg film-coated tablets's risks and uncertainties (missing information).

Ticagrelor SUN 60 mg and 90 mg film-coated tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ticagrelor SUN 60 mg and 90 mg film-coated tablets should be used.

#### **I. The medicine and what it is used for**

Ticagrelor SUN 60 mg and 90 mg film-coated tablets 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 (see SmPC sections 4.2 and 5.1).

It contains ticagrelor as the active substance and it is given by the oral route.

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

Important risks of Ticagrelor SUN 60 mg and 90 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Ticagrelor SUN 60 mg and 90 mg film-coated tablets'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 (e.g. with or without prescription) can help to minimise its risks.

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

If important information that may affect the safe use of Ticagrelor SUN 60 mg and 90 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

## **II.A List of important risks and missing information**

Important risks of Ticagrelor SUN 60 mg and 90 mg film-coated tablets are risks that need special risk management activities to further investigate or minimise 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 Ticagrelor SUN 60 mg and 90 mg film-coated tablets. 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).

<b>List of important risks and missing information</b>	
<b>Important identified risks</b>	<b>Increased risk of bleeding</b>
<b>Important potential risks</b>	<b>None</b>
<b>Missing information</b>	<b>Long-term use in patients with prior ischaemic stroke</b>

## **II.B Summary of important risks**

The safety information in the proposed Product Information is aligned to the reference medicinal product<sup>2</sup>.

## **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 SUN 60 mg and 90 mg film-coated tablets.

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

There are no studies required for Ticagrelor SUN 60 mg and 90 mg film-coated tablets.