

## **Part VI: Summary of the risk management plan**

### Summary of risk management plan for TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets (perindopril tert-butylamine and amlodipine besylate)

This is a summary of the risk management plan (RMP) for TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets.

The RMP details important risks of TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets, how these risks can be minimised, and how more information will be obtained about risks of TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets and uncertainties (missing information).

Summary of product characteristics (SmPC) of TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets and package leaflet give essential information to healthcare professionals and patients on how TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets should be used.

Important new concerns or changes to the current ones will be included in updates of RMP of TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets.

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

TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets as substitution therapy for treatment of essential hypertension and/or stable coronary artery disease in patients already controlled with perindopril and amlodipine given concurrently at the same dose level.

TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets contain a fixed combination of Perindopril tert-butylamine and amlodipine besylate as active substances and it is given by oral route of administration.

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

Important risks of TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets together with measures to minimise such risks and the proposed studies for learning more about risks of TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets, are outlined below.

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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;

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*.

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

The fixed combination perindopril/amlodipine is included in HaRP project. According to HaRP (Harmonisation of RMP Project) - methodology of harmonising RMPs (CMDh/402/2019, Rev. 1 April 2021), if there not additional pharmacovigilance activities and additional risk minimisation measures in place and there are not targeted questionnaires in place for a specific active substances or for a fixed dose combination of active substances, all safety concerns could be removed from the safety concerns list of the product [https://www.hma.eu/fileadmin/dateien/Human\\_Medicines/CMD\\_h\\_/Pharmacovigilance\\_Legislation/RMPs/HaRP\\_ARs/Perindopril-Amlodipine\\_05\\_2021\\_HaRP\\_AR.pdf](https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/RMPs/HaRP_ARs/Perindopril-Amlodipine_05_2021_HaRP_AR.pdf).

Table part VI-IIa: List of important risks and missing information

<b>Summary of safety concerns</b>	
<b>Important identified risks</b>	None
<b>Important potential risks</b>	None
<b>Missing information</b>	None

**II.B Summary of important risks**

A reported in the section II.A this section is considered not applicable

**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 TENAMPER 8 mg/5 mg, 4 mg/5 mg, 8 mg/10 mg, 4 mg/10 mg, tablets.

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

Not applicable.