

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.

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 .

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

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	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.