## Part VI: Summary of the risk management plan

## Summary of risk management plan for PRETERAX (Perindopril/Indapamide)

This is a summary of the risk management plan (RMP) for PRETERAX.

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

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

PRETERAX contains perindopril and indapamide as the active substances and it is given by oral route.

Perindopril tert-butylamine/indapamide 2 mg / 0.625 mg and perindopril arginine/indapamide 2.5 mg / 0.625 mg are authorised for essential hypertension in adults.

Perindopril tert-butylamine/indapamide 4 mg / 1.25 mg and perindopril arginine/indapamide 5 mg / 1.25 mg: are authorised for essential hypertension in patients whose blood pressure is not adequately controlled on perindopril alone.

Perindopril tert-butylamine/indapamide 8 mg / 2.5 mg and perindopril arginine/indapamide 10 mg / 2.5 mg are authorised for substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril and indapamide given concurrently at the same dose level.

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

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

There is no important risk of PRETERAX that needs special risk management activities to further investigate or minimise the risk or missing information associated with the use of PRETERAX.

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

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

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 PRETERAX.

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

There are no studies required for PRETERAX.