

Part VI: Summary of the risk management plan

Summary of risk management plan for COVERAM and VIACORAM (Perindopril/Amlodipine)

This is a summary of the risk management plan (RMP) for Coveram® and Viacoram®.

Coveram and Viacoram's summary of product characteristics (SmPC) and their package leaflets give essential information to healthcare professionals and patients on how Coveram and Viacoram should be used.

I. The medicine and what it is used for

Coveram is authorised for Essential Hypertension and for Coronary artery disease (see SmPC for the full indication).

Viacoram is authorised for Essential Hypertension (see SmPC for the full indication).

These products contain Perindopril and Amlodipine as the active substances and are given by oral use.

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

No important risks were identified for Coveram and Viacoram and no activities to minimise the risks are deemed necessary.

II.A List of important risks and missing information

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

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 Coveram and Viacoram.

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

There are no studies required for Coveram and Viacoram.