SUMMARY OF RISK MANAGEMENT PLAN FOR SERINXAM (PERINDOPRIL ARGININE/INDAPAMIDE/AMLODIPINE)

This is a summary of the risk management plan (RMP) for Serinxam. The RMP details important risks of Serinxam, how these risks can be minimised, and how more information will be obtained about Serinxam's risks and uncertainties (missing information).
Serinxam's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Serinxam should be used.

This summary of the RMP for Serinxam should be read in the context of all other information including the assessment report of the evaluation and its plain language summary, all of which is part of the Public Assessment Report where available.

Important new concerns or changes to the current ones will be included in updates of Serinxam's RMP.

I. The medicine and what it is used for

Serinxam is authorized for substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril/amlodipine fixed dose combination and indapamide, taken at the same dose level (see SmPC for the full indication). It contains perindopril, indapamide and amlodipine as the active substances and used orally.

II. Risks associated with the medicine and activities to minimize or further characterize the risks.

No important risks were identified for Serinxam® and no activities to minimize the risks are deemed necessary beyond the measures described below. Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

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

List of important risks and missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

A Important identified risks	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A
Risk minimisation measures	N/A
Additional pharmacovigilance activities	N/A

B Important potential risks	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A
Risk minimisation measures	N/A
Additional pharmacovigilance activities	N/A

C Missing information	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A

Risk minimisation measures	N/A
Additional pharmacovigilance activities	N/A

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization.

There are no studies which are conditions of the marketing authorisation or specific obligation of Serinxam.

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

There are no studies required for Serinxam.