Part VI: Summary of the risk management plan

Summary of risk management plan for Cosyrel®/Asembix® (Bisoprolol/Perindopril)

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

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

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

I. The medicine and what it is used for

Cosyrel® and Asembix® (strengths 5 mg/5 mg & 10 mg/5 mg) are authorised as substitution therapy for treatment of hypertension and/or stable coronary artery disease and/or stable chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level (see SmPC for the full indication).

Cosyrel® and Asembix® (strengths 5 mg/10 mg & 10 mg/10 mg) are authorised as substitution therapy for treatment of hypertension and/or stable coronary artery disease in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level (see SmPC for the full indication).

These products contain Bisoprolol and Perindopril as the active substances and are taken orally once daily, preferably in the morning.

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

No important risks were identified for Cosyrel® and Asembix® and no activities to minimise the risks are deemed necessary beyond the measures described 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;
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

There is no important risk of Cosyrel® and Asembix® 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

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 bisoprolol/perindopril.

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

There are no studies required for bisoprolol/perindopril.