Part VI: Summary of the risk management plan

Summary of risk management plan Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets (Nebivolol)

This is a summary of the risk management plan (RMP) for Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets. The RMP details important risks of Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets, how these risks can be minimised, and how more information will be obtained about Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets' risks and uncertainties (missing information).

Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets RMP.

I. The medicine and what it is used for

Nebivolol tablets are indicated for:

Hypertension:

Treatment of essential hypertension.

Chronic heart failure (CHF):

Treatment of stable mild and moderate chronic heart failure in addition to standard therapies in elderly patients >70 years.

It contains Nebivolol as the active substance and is given orally.

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

Important risks Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets together with measures to minimise such risks and the proposed studies for learning more about Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets' risks, 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;
- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR (if applicable) assessment and signal management activity, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 authorization or specific obligation of Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets.

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

There are no studies required for Nebivolol 1.25 mg /2.5 mg /5 mg and 10 mg tablets as post-authorisation development plan.