Part VI: Summary of the risk management plan

Summary of risk management plan for Nebivolol Krka (nebivolol)

This is a summary of the risk management plan (RMP) for nebivolol by Krka. The RMP details important risks of nebivolol by Krka, how these risks can be minimised, and how more information will be obtained about nebivolol by Krka's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Nebivolol by Krka is authorised for treatment of hypertension and chronic heart failure (see SmPC for the full indication). It contains nebivolol as the active substance and it is given by orally.

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

Important risks of nebivolol by Krka, together with measures to minimise such risks and the proposed studies for learning more about nebivolol by Krka's 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 assessment – so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of nebivolol by Krka is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of nebivolol by Krka 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 by Krka. 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);

Summary of safety concerns	
Important identified risks	Heart problems (Cardiovascular disorders)
	Blood pressure decreased (Hypotension)
	Difficulty in breathing because of bronchial spasm (Bronchospasm)
	Masking of symptoms of hypoglycaemia and hyperthyroidism
	Allergies (Hypersensitivity, including anaphylactic reactions)
	Psoriasis (exacerbation)
	Drug interactions
Important potential risks	Use during pregnancy
	Bend and painful penis

Summary of safety concerns	
	(Peyronie's disease)
	Oculo-mucocutaneous toxicity
Missing information	Use in children and adolescents
	Use during lactation

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 authorisation or specific obligation of nebivolol by Krka.

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

There are no studies required for nebivolol by Krka.