Summary of risk management plan for amlodipine/valsartan/hydrochlorothiazide by Krka

This is a summary of the risk management plan (RMP) for amlodipine/valsartan/hydrochlorothiazide by Krka. The RMP details important risks of amlodipine/valsartan/hydrochlorothiazide by Krka and how more information will be obtained about amlodipine/valsartan/hydrochlorothiazide by Krka's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Amlodipine/valsartan/hydrochlorothiazide by Krka is authorised for treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (see SmPC for the full indication). It contains amlodipine/valsartan/hydrochlorothiazide as the active substance and it is given orally.

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

Important risks of amlodipine/valsartan/hydrochlorothiazide by Krka, together with measures to minimise such risks and the proposed studies for learning more about amlodipine/valsartan/hydrochlorothiazide 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*.

II.A List of important risks and missing information

Important risks of amlodipine/valsartan/hydrochlorothiazide 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 amlodipine/valsartan/hydrochlorothiazide 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	Hypotension
	Serum electrolyte changes
	Renal impairment (especially in patients with renal artery stenosis, pre-existing renal impairment, heart failure, post-myocardial infarction, dual blockade of RAAS)
	Teratogenicity
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 authorisation or specific obligation of amlodipine/valsartan/hydrochlorothiazide by Krka.

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

There are no studies required for amlodipine/valsartan/hydrochlorothiazide by Krka.