Summary of risk management plan for Febuxostat Krka (febuxostat)

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

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

This summary of the RMP for Febuxostat Krka should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Febuxostat Krka is authorised for treatment of hyperuricaemia (see SmPC for the full indication). It contains febuxostat as the active substance and it is given orally.

Further information about the evaluation of Febuxostat Krka's benefits can be found in Febuxostat Krka's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/febuxostat-krka.

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

Important risks of Febuxostat Krka together with measures to minimise such risks and the proposed studies for learning more about Febuxostat 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, 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 Febuxostat 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 Febuxostat 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	Serious skin / hypersensitivity reactions
	Rhabdomyolysis
	Drug-drug interaction with azathioprine or mercaptopurine
Important potential risks	Cardiovascular events
	Hepatic events
	Renal events
	Neuropsychiatric events
	Haematological / Bleeding events
	Thyroid events
	Off label use in the paediatric population (TLS specific)
Missing information	Children and adolescents
	Subjects in whom the rate of serum urate formation is greatly increased (e.g Lesch-Nyhan syndrome)

Summary of safety concerns	
	Organ transplantation
	Severe hepatic impairment
	Pregnancy and lactation
	Limited experience in: severe renal impairment, moderate hepatic impairment
	Interaction with standard therapy of haematological malignancies (TLS specific)
	Off label use in patients with solid tumors (TLS specific)

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 Febuxostat Krka.

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

There are no studies required for Febuxostat Krka.