Summary of risk management plan for Febuxostat 80 and 120 mg film-coated tablets (Febuxostat)

This is a summary of the risk management plan (RMP) for Febuxostat 80 and 120 mg film-coated tablets. The RMP details important risks of Febuxostat 80 and 120 mg film-coated tablets, and how more information will be obtained about Febuxostat 80 and 120 mg film-coated tablets 's risks and uncertainties (missing information).

Febuxostat 80 and 120 mg film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Febuxostat 80 and 120 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Febuxostat 80 and 120 mg film-coated tablet's RMP.

I. The medicine and what it is used for

Febuxostat 80 mg is authorised for: the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

Febuxostat 120 mg is authorised for: the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

Febuxostat 120 mg film-coated tablets is also indicated for the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS).

Febuxostat 80 and 120 mg film-coated tablets is indicated in adults (see SmPC for the full indication).

It contains Febuxostat as the active substance, and it is given by oral route.

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

Important risks of Febuxostat 80 and 120 mg film-coated tablets together with measures to minimise such 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.

If important information that may affect the safe use of Febuxostat 80 and 120 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Febuxostat 80 and 120 mg film-coated 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 Febuxostat 80 and 120 mg film-coated 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).

List of important risks and missing information	
Important identified risks	- Serious skin / hypersensitivity reactions - Rhabdomyolysis - Drug-drug interaction with azathioprine or mercaptopurine - Cardiovascular events
Important potential risks	- Hepatic events - Renal events - Neuropsychiatric events - Haematological / Bleeding events - Thyroid events - Off label use in the paediatric population (TLS specific)
Missing information	No experience in: - Children and adolescents - Subjects in whom the rate of serum urate formation is greatly increased (e.g. Lesch-Nyhan syndrome) - Organ transplantation - Severe hepatic impairment - Pregnancy and lactation - Off label use in patients with solid tumors (TLS specific) - Interaction with standard therapy of hematological malignancies (TLS specific) Limited experience in: - Severe renal impairment - Moderate hepatic impairment

II.B Summary of important risks

The safety information in the 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 80 and 120 mg film-coated tablets.

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

There are no studies required for Febuxostat 80 and 120 mg film-coated tablets.