Part VI: Summary of the risk management plan

Summary of risk management plan for Allopurinol Orion (allopurinol)

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

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

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

I. The medicine and what it is used for

Allopurinol Orion 100 mg and 300 mg tablets are authorised for prevention or treatment of following conditions in adults:

- All forms of hyperuricaemia not controllable by diet including secondary hyperuricaemia of differing origin and in clinical complications of hyperuricaemic states, particularly manifest gout, urate nephropathy and for the dissolution and prevention of uric acid stones
- The management of recurrent mixed calcium oxalate stones in concurrent hyperuricaemia, when fluid, dietary and similar measures have failed.

In addition Allopurinol Orion 100 mg tablets are authorised for prevention or treatment of following conditions in children and adolescents

- Secondary hyperuricaemia of differing origin
- Uric acid nephropathy during treatment of leukaemia
- Hereditary enzyme deficiency disorders, Lesch-Nyhan syndrome (partial or total hypoxanthin-guanin phosphoribosyl transferase deficiency) and adenine phosophoribosyl transferase deficiency.

Allopurinol Orion contains allopurinol as the active substance and it is given by mouth.

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

Important risks of Allopurinol Orion, together with measures to minimise such risks and the proposed studies for learning more about Allopurinol Orion'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.

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

II.A List of important risks and missing information

Important risks of Allopurinol Orion 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 Allopurinol Orion. 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 hypersensitivity reactions
Important potential risks	Concomitant administration of ampicillin/amoxicillin
Missing information	Administration during pregnancy and lactation

II.B Summary of important risks

Safety concerns are adequately addressed in Product Information.

II.C Post-authorisation development plan

There are no studies which are conditions of the marketing authorisation or specific obligation of Allopurinol Orion.