Part VI: Summary of the risk management plan

Summary of risk management plan for imatinib

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

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

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

I. The medicine and what it is used for

Imatinib is authorised for treatment of several types of neoplastic diseases in both adult and paediatric populations, primarily haematological neoplastic diseases (chronic myeloid leukaemia, acute lymphoblastic leukaemia, myelodysplastic/myeloproliferative diseases, advanced hypereosinophilic syndrome) as well as gastrointestinal stromal tumours (GIST) and dermatofibrosarcoma protuberans (DFSP) (see SmPC for the full indication). It contains imatinib as the active substance and it is taken orally.

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

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

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

II.A List of important risks and missing information

Important risks of imatinib are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 imatinib. 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:	Hypothyroidism in thyroidectomy patients undergoing levothyroxine replacement
	Hepatotoxicity
	Fluid retention
	Use in patients with HES/CEL and MDS/MPD associated with high eosinophil levels
	Tumour lysis syndrome
	Myelosuppression
	Renal impairment
Important potential risks:	Use in patients with renal impairment
	Use in patients with cardiac disease
	Growth retardation
Missing information:	Use in pediatric patients with CMP below 2 years of age
	Use in pediatric and adolescent patients with MDS/MPD, DFSP and HES/CEL
	Effect on fertility

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 imatinib.

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

There are no studies required for imatinib.