sRMP

Dasatinib

Part VI: Summary of the risk management plan

Summary of risk management plan for Dasatinib film-coated tablets

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

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

I. The medicine and what it is used for

Dasatinib is an anticancer medicine.

It is used to treat *adults* with the following types of leukaemia (cancer of the white blood cells):

- newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase.
- chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib mesilate.
- Ph+ acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.

Dasatinib is also used to treat *children* with

- newly diagnosed Ph+ CML in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib.
- newly diagnosed Ph+ ALL in combination with chemotherapy.

See SmPC for the full indication. It contains dasatinib as the active substance and it is given by mouth. Dasatinib is available as film-coated tablets in strengths of 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg.

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

Important risks of Dasatinib, together with measures to minimise such risks and the proposed studies for learning more about Dasatinib'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 Dasatinib is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dasatinib 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 Dasatinib. 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	• Myelosuppression • Fluid retention • Bleeding related events • QT Prolongation • Pulmonary Arterial Hypertension (PAH) • Pregnancy related malformative or foeto/neonatal toxicity
Important potential risks	• Severe hepatotoxicities • Direct cardiotoxic effects (e.g. cardiomyopathy) • Growth and development disorders and bone mineral metabolism disorders • Toxic skin reactions • CYP3A4 drug interactions • Hepatitis B Virus (HBV) reactivation • Nephrotic Syndrome
Missing information	• Carcinogenicity • Pediatric population data ○ for patients < 1 year • Reproductive and lactation data

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 Dasatinib.

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

There are no studies required for Dasatinib.