Part VI: Summary of the risk management plan

Summary of risk management plan for:

Dasatinib Pharmascience 20 mg film-coated tablets, (dasatinib)
Dasatinib Pharmascience 50 mg film-coated tablets, (dasatinib)
Dasatinib Pharmascience 70 mg film-coated tablets, (dasatinib)
Dasatinib Pharmascience 80 mg film-coated tablets, (dasatinib)
Dasatinib Pharmascience 100 mg film-coated tablets, (dasatinib)
Dasatinib Pharmascience 140 mg film-coated tablets (dasatinib)

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

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

I. The medicine and what it is used for

Dasatinib Pharmascience is authorised for the treatment of adult patients with 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 mesylate, Ph+ acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy. Dasatinib Pharmascience is also authorised for the treatment of paediatric patients with newly diagnosed Ph+ CML in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib. (see SmPC for the full indication).
It contains dasatinib as the active substance and it is given by oral administration as film-coated tablets.

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

Important risks of Dasatinib Pharmascience, together with measures to minimise such risks and the proposed studies for learning more about Dasatinib Pharmascience’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, including adverse reaction-specific follow-up questionnaires and PSUR assessment, 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 Dasatinib Pharmascience is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dasatinib Pharmascience 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 Pharmascience. 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 (eg, Cardiomyopathy) • Growth and development disorders and bone mineral metabolism disorders in the paediatric population • Toxic Skin Reactions • CYP3A4 Drug Interactions • HBV Reactivation • Nephrotic Syndrome
Missing information	• Carcinogenicity • Paediatric data: o for patients < 1 yr • 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 Pharmascience.

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

There are no studies required for Dasatinib Pharmascience.