SUMMARY OF THE RISK MANAGEMENT PLAN FOR SPRYCEL®
(DASATINIB)

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Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of SPRYCEL® (Dasatinib) is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of SPRYCEL® (Dasatinib) in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Bristol-Myers Squibb SA is fully responsible for the accuracy and correctness of the content of the published summary RMP of SPRYCEL® (Dasatinib).

SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for SPRYCEL (dasatinib)

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

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

This summary of the RMP for SPRYCEL should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

SPRYCEL is authorised for use in adults with newly diagnosed Philadelphia chromosome-positive (Ph+) Chronic Myeloid Leukaemia (CML) in Chronic Phase (CP); adults with CP, Accelerated Phase (AP), or Blast Phase (BP) CML with resistance or intolerance to prior therapy including imatinib; and Ph+ Acute Lymphoblastic Leukaemia (ALL) and lymphoid BP CML with resistance or intolerance to prior therapy. (see SmPC for the full indication). SPRYCEL is authorised for use in paediatric patients with newly diagnosed Ph+ CML in CP, or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib. It contains dasatinib as the active substance and it is given orally by tablet or powder for oral suspension (PFOS).

Further information about the evaluation of SPRYCEL’s benefits can be found in SPRYCEL’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/sprycel.

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

Important risks of SPRYCEL, together with measures to minimise such risks and the proposed studies for learning more about SPRYCEL'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 (eg, with or without prescription) can help to minimise its risks

Together, these measures constitute routine risk minimisation measures.

Information about adverse reactions is collected continuously and regularly analysed, including 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 SPRYCEL is not yet available, it is listed under 'missing information' below.

II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of SPRYCEL 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 SPRYCEL. 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 (eg, on the long-term use of the medicine).

List of important risks and missing information

Important identified risks	None
Important potential risks	Growth and development disorders and bone mineral metabolism disorders in the paediatric population
Missing information	None

II.B SUMMARY OF IMPORTANT RISKS

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Growth and Development Disorders and Bone Mineral Metabolism Disorders in Paediatric Population	
Evidence for linking the risk to the medicine	Children with leukaemia who are receiving standard chemotherapy, radiation therapy or stem cell transplants are at increased risk for growth and development disorders and decreased bone mineralization as a result of their diagnosis and/or treatments.
Risk factors and risk groups	Patients of pre-pubertal age may be at increased risk for any potential growth-related effects. Paediatric patients with leukaemia or receiving standard chemotherapy, radiation therapy or stem cell transplants are at increased risk for growth and development disorders and decreased bone mineralization as a result of their diagnosis and/or treatments. It is unknown if treatment with dasatinib in this setting will alter this risk.
Risk minimisation measures	SmPC Section 4.8

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 of SPRYCEL.

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

There are no studies required for SPRYCEL.