

Part VI: Summary of the risk management plan

Summary of risk management plan for Bosutinib STADA 100 mg, 400 mg and 500 mg film-coated tablets (Bosutinib)

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

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

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

I. The medicine and what it is used for

Bosutinib STADA is indicated for the treatment of adult patients with:

- newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML).
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

It contains bosutinib as the active substance, and it is given orally (see SmPC for the full indication).

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

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

II.A List of important risks and missing information

Important risks of Bosutinib STADA 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 Bosutinib STADA. 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	<ul style="list-style-type: none"> • None
Important potential risks	<ul style="list-style-type: none"> • None
Missing information	<ul style="list-style-type: none"> • Use in Paediatric Patients (age: ≤17 years)

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 Bosutinib STADA.

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

There are no studies required for Bosutinib STADA.

Summary of risk management plan for Bosutinib STADA AG 100 mg, 400 mg and 500 mg film-coated tablets (Bosutinib)

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

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

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

I. The medicine and what it is used for

Bosutinib STADA AG is indicated for the treatment of adult patients with:

- newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML).
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

It contains bosutinib as the active substance, and it is given orally (see SmPC for the full indication).

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

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

II.A List of important risks and missing information

Important risks of Bosutinib STADA AG 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 Bosutinib STADA AG. 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	
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Missing information	<ul style="list-style-type: none"> • Use in Paediatric Patients (age: ≤17 years)

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 Bosutinib STADA AG.

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

There are no studies required for Bosutinib STADA AG.