NEWBURY

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Bosutinib Newbury (Bosutinib)

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

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

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

I. The medicine and what it is used for

Bosutinib is authorised 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.

(See SmPC for the full indication). It contains bosutinib as the active substance and it is given by oral administration.

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

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

II.A List of important risks and missing information

Important risks of Bosutinib Newbury 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 Newbury.

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	None
Important potential risks	None
Missing information	Use in Paediatric Patients (age: ≤17 years)

II.B Summary of important risks

Safety concerns are adequately addressed in the product information and 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.

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

There are no studies required for Bosutinib.