Part VI: Summary of the risk management plan

Summary of risk management plan for Webrix

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

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

I. The medicine and what it is used for

Webrix as monotherapy is indicated for the treatment of:

- Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s);
- Adult patients with locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy

See SmPC for the full indication. It contains afatinib as the active substance and it is given orally.

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

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

II.A List of important risks and missing information

Important risks of Webrix 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 Webrix. 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);

Summary of safety concerns	
Important identified risks	– Interstitial lung disease (ILD) – Hepatic impairment – Gastrointestinal perforation
Important potential risks	– Decreased left ventricular ejection fraction (LVEF)/heart failure – Developmental toxicity – Hypersensitivity reactions – Poor survival following off-label use in combination with vinorelbine in breast cancer – Use in combination with chemotherapy
Missing information	– None

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 Webrix.

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

There are no studies required for Webrix.