

Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan For Gefitinib 250 mg film-coated tablet(Gefitinib)

This is a summary of the risk management plan (RMP) for Gefitinib 250 mg film-coated tablet, (hereinafter referred to as Gefitinib). The RMP details important risks of Gefitinib, how these risks can be minimised, and how more information will be obtained about Gefitinib's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Gefitinib is authorised for monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) (see SmPC for the full indication). It contains gefitinib 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 Gefitinib, together with measures to minimise such risks and the proposed studies for learning more about Gefitinib'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 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 gefitinib is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Gefitinib 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 Gefitinib. 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).

Table 5: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> • Interstitial lung disease • Hepatitis • Gastrointestinal perforation • Drug-drug interactions: interactions with inducers and inhibitors of CYP3A4 isoenzyme; interactions mediated by CYP2D6 isoenzyme; interactions with medicines that cause significant sustained elevations of gastric pH
Important potential risks	<ul style="list-style-type: none"> • Haemorrhage events (including gastrointestinal haemorrhage and tumour haemorrhage) • Cerebrovascular events • Drug interactions: interactions with oral anticoagulants
Missing information	<ul style="list-style-type: none"> • Use in pregnant or lactating women • Use in patients with severe renal impairment

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 Gefitinib.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Gefitinib.