Part VI: Summary of the risk management plan

Summary of risk management plan for Gefitinib Orion (gefitinib)

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

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

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

I. The medicine and what it is used for

Gefitinib Orion is authorised for treatment of adults who have non-small-cell lung cancer that is locally advanced or metastatic (when cancer cells have spread from the original site to other parts of the body). It is used in patients whose cancer cells have a mutation in the genes that make a protein called epidermal-growth-factor receptor (EGFR) (see SmPC for the full indication). It contains gefitinib as the active substance and it is taken by mouth.

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

Important risks of Geifitinib Orion, together with measures to minimise such risks and the proposed studies for learning more about Gefitinib Orion'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.

If important information that may affect the safe use of Gefitinib Orion is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Gefitinib Orion 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 Orion. 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	Interstitial lung disease (ILD)
	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	Haemorrhage events (including gastrointestinal haemorrhage and tumour haemorrhage)
	Cerebrovascular events
	Drug-drug interactions: interactions with oral anticoagulants
Missing information	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

There are no studies required for Gefitinib Orion.