Part VI: Summary of the risk management plan for Vinorelbine Orifarm

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

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

I. The medicine and what it is used for

Vinorelbine Orifarm is indicated for use for non-small cell lung cancer and for advanced breast cancer in adults to whom no other treatment can be administered. It contains vinorelbine and is given as a soft capsule orally.

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

Important risks of Vinorelbine Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Vinorelbine Orifarm´s risks, are outlined below.

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish, Finnish, Norwegian and Swedish Medicines Agencies.
- The product is prescription-only medicine.

These measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Vinorelbine Orifarm 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 Vinorelbine Orifarm. 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	• Bone marrow depression • Infection

Summary of safety concerns	
	• Corneal ulceration • Gastrointestinal Disorder • Interaction with enzyme called CYP3A4 inducers and inhibitors
Important potential risks	• Genotoxicity • Teratogenicity
Missing information	• Carcinogenic potential • Use during breast feeding • Use in children

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 Vinorelbine Orifarm.

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

There are no studies required for Vinorelbine Orifarm.