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

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

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

I. The medicine and what it is used for

Modafinil Orifarm is authorised for treatment of adults who suffer from narcolepsy to help them to stay awake. Narcolepsy is a condition that causes excessive daytime sleepiness and a tendency to fall asleep suddenly in inappropriate situations (sleep attacks).

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

Important risks of Modafinil Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Modafinil 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 and Swedish Medicines Agency.
- The medicine's is prescription only medicine and must be prescribed by a doctor.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Modafinil e 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 Modafinil 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	• Cardiovascular effects • Skin and hypersensitivity reactions, including Stevens-Johns syndrome, toxic epidermal necrolysis, drug rash with eosinophila and systemic symptoms. • Nervous system disorders • Psychiatric related events such as anxiety,

Summary of safety concerns	
	suicidal attempts and ideation, psychotic or manic symptoms, worsening of aggressive or hostile behaviour, and depression.
Important potential risks	• Off-label use inclusive paediatric off-label use. • Abuse, misuse and diversion
Missing information	• Use in pregnancy and lactation • Use in the elderly

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 Modafinil Orifarm.

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

There are no studies required for Modafinil Orifarm.