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.

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

I. The medicine and what it is used for

Modafinil Orifarm is indicated in adults for the treatment of excessive sleepiness associated with narcolepsy with or without cataplexy.

Excessive sleepiness is defined as difficulty maintaining wakefulness and an increased likelihood of falling asleep in inappropriate situations (see SmPC for the full indication).

It contains modafinil as the active substance and it is given by tablet 100 mg.

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.

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*.

In the case of Modafinil Orifarm, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

II.A List of important risks and missing information

Important risks of Modafinil 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	None
Important potential risks	• Misuse, abuse and diversion • Teratogenicity
Missing information	None

II.B Summary of important risks

Important potential risk: Misuse, abuse and diversion	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 2 Additional risk minimisation measures: None
Important potential risk: Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 and 4.6 PL section 2 Additional risk minimisation measures: Direct Healthcare Professional Communication (DHPC)

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.