Part VI: Summary of the risk management plan

Summary of risk management plan for Modafinil Forza, film-coated tablets, 100 mg

This is a summary of the risk management plan (RMP) for Modafinil Forza, film-coated tablets, 100 mg. The RMP details important risks of Modafinil Forza, how these risks can be minimised, and how more information will be obtained about Modafinil Forza's risks and uncertainties (missing information).

Modafinil Forza’s Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Modafinil Forza's should be used.

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

I. The medicine and what it is used for

Modafinil Forza is proposed for authorization for the treatment of excessive sleepiness associated with narcolepsy with or without cataplexy in adults (see SmPC for the full indication). It contains modafinil as the active substance, for oral administration.

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

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

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.

II.A List of important risks and missing information

Important risks of Modafinil Forza 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 drug use. 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	• **None**
Important potential risks	• **Misuse, abuse and diversion** • **Teratogenicity**
Missing information	• **None**

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

NA