Part VI: Summary of the risk management plan

Summary of risk management plan Flucarin (fluoxetine)

This is a summary of the risk management plan (RMP) for Flucarin. The RMP details important risks of Flucarin and how more information will be obtained about Flucarin risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Flucarin is authorised for major depressive episodes, obsessive-compulsive disorder, and bulimia.
It contains fluoxetine as the active substance, and it is administered orally.

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

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

Measures to minimize the risks identified for medicinal products are:

- 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 medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimize its risks.

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

If important information that may affect the safe use of Flucarin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Flucarin 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 Flucarin. 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	None
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

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 Flucarin.

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

There are no studies required for Flucarin.