13 Part VI: Summary of the risk management plan for Mirtazapine, 15 mg, 30 mg and 45 mg, Film coated tablets and orodispersible tablets

This is a summary of the risk management plan (RMP) for mirtazapine, 15 mg, 30 mg and 45 mg, film coated tablets and orodispersible tablets. The RMP details important risks of mirtazapine, film-coated tablets and orodispersible tablets, how these risks can be minimized, and how more information will be obtained about mirtazapine, film-coated tablet's and orodispersible tablet's risks and uncertainties (missing information).

Mirtazapine, film-coated tablet's and orodispersible tablet's summary of product characteristics (SmPC) and its package leaflets give essential information to healthcare professionals and patients on how mirtazapine, film-coated tablets and orodispersible tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the mirtazapine, film-coated tablet's and orodispersible tablet's RMP.

13.1 Part VI: I. The medicine and what it is used for

Mirtazapine, film-coated tablets and orodispersible tablets are authorized for:

Mirtazapine is indicated in adults for the treatment of episodes of major depression.

It contains mirtazapine as an active substance and is taken orally as film-coated tablets (15 mg, 30 mg and 45 mg) and orodispersible tablets (15 mg, 30 mg and 45 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of mirtazapine, film-coated tablets and orodispersible tablets, together with measures to minimize such risks and the proposed studies for learning more about mirtazapine, film-coated tablet's and orodispersible tablet's risks, are outlined below.

Measures to minimize 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 authorized 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 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 analyzed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of mirtazapine, film-coated tablets and orodispersible tablets are risks that need special risk management activities to further investigate or minimize 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 mirtazapine, film-coated tablets and orodispersible tablets. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	QT prolongation and/or ventricular arrhythmia (e.g. Torsades de Pointes)
Important potential risks	None
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies, which are conditions of the marketing authorization or specific obligation for mirtazapine, film-coated tablets and orodispersible tablets.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for mirtazapine, film-coated tablets and orodispersible tablets.