

Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for MIRTAZAPINE 15 mg, 30 mg, 45 mg film-coated tablets

This is a summary of the risk management plan (RMP) for MIRTAZAPINE 15 mg, 30 mg, 45 mg film-coated tablets (hereinafter referred to as Mirtazapine). The RMP details important risks of Mirtazapine, how these risks can be minimised, and how more information will be obtained about Mirtazapine's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Mirtazapine is authorised in adults for the treatment of episodes of major depression (see SmPC for the full indication). It contains Mirtazapine as the active substance and it is taken orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Mirtazapine, together with measures to minimise such risks and the proposed studies for learning more about Mirtazapine's risks, if any, 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*.

II.A List of Important Risks and Missing Information

Important risks of Mirtazapine 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 Mirtazapine. 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 5: Summary of Safety Concerns

Summary of safety concerns	
Important identified risks	<ul style="list-style-type: none"> • QT prolongation and/or ventricular arrhythmia (e.g. Torsades de Pointes)
Important potential risks	<ul style="list-style-type: none"> • None
Missing information	<ul style="list-style-type: none"> • None

II.B Summary of Important Risks

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

Table 6: Summary of Important Risks

Important identified risk: QT prolongation and/or ventricular arrhythmia (e.g. Torsades de Pointes)	
Evidence for linking the risk to the medicine	SmPC, scientific literature
Risk factors and risk groups	The risk of QT prolongation and/or ventricular arrhythmias (e.g. Torsades de Pointes) may be increased with concomitant use of medicines which prolong the QTc interval (e.g. some antipsychotics and antibiotics). Risk factors for QT prolongation include patients with a personal or family history of QT prolongation, congestive heart failure, bradyarrhythmias and electrolyte abnormalities, patients with diagnosed or suspected Congenital Long QT Syndrome.
Risk minimisation measures	No additional risk minimisation measures proposed.

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 Mirtazapine.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Mirtazapine.