NEWBURY

EU RISK MANAGEMENT PLAN FOR
Mirtazapin Newbury (Mirtazapine)

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Mirtazapine

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

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

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

I. The medicine and what it is used for

Mirtazapine Newbury 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 Newbury together with measures to minimise such risks and the proposed studies for learning more about Mirtazapine Newbury 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.

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II.A List of important risks and missing information

Summary of safety concerns	
Important identified risks	• QT prolongation and/or ventricular arrhythmia (e.g. Torsades de Pointes)
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

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 Mirtazapin Newbury.

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

There are no studies required for Mirtazapine Newbury.