

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Atomoxetine Mylan

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

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

I. The medicine and what it is used for

Atomoxetine is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children aged 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD.

In adults, the presence of symptoms of ADHD that were pre-existing in childhood should be confirmed. Third-party corroboration is desirable and atomoxetine should not be initiated when the verification of childhood ADHD symptoms is uncertain. Diagnosis cannot be made solely on the presence of one or more symptoms of ADHD. Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in 2 or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life. It contains atomoxetine as the active substance and it is given by 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg Hard Capsules of oral administration.

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

Important risks of Atomoxetine Mylan, together with measures to minimise such risks and the proposed studies for learning more about Atomoxetine Mylan'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;

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- 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 public (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 events is collected continuously and regularly analysed, including PSUR assessment, 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 Atomoxetin Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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 Atomoxetin Mylan. 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/use in special patient populations etc.);

Table 4 Part VI: Summary of safety concerns

List of important risks and missing information	
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 Atomoxetin Mylan

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

There are no studies required for Atomoxetin Mylan