Part VI: Summary of the risk management plan

Summary of risk management plan for Atomoxetine 10/18/25/40/60/80/100 mg, Hard Capsules (Atomoxetine hydrochloride)

This is a summary of the risk management plan (RMP) for Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules. The RMP details important risks of Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules, how these risks can be minimised, and how more information will be obtained about Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules' risks and uncertainties (missing information).

Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules' should be used.

Important new concerns or changes to the current ones will be included in updates of Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules' RMP.

I. The medicine and what it is used for

Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules is authorized for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme (see SmPC for the full indication). It contains Atomoxetine hydrochloride as the active substance and it is given by oral route.

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

Important risks of Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules' 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 the case of Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment and signal management activity, 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 Atomoxetine 10/18/25/40/60/80/100 mg, Hard Capsules (Atomoxetine hydrochloride) is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules 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 Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules. 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);

List of important risks and missing information	
Important identified risks	• Suicidal ideation • Hepatic injury • Increased blood pressure and increased heart rate • Peripheral vascular instability (Raynaud's phenomenon)
Important potential risks	• Cardiovascular and cerebrovascular outcomes o QTc prolongation o Myocardial ischaemia o Tachyarrhythmia o Cerebrovascular accident • Aggression/hostility • Seizures
Missing information	• None

II.B Summary of important risks with additional risk minimisation measures

Important Identified Risks: Increased blood pressure and increased heart rate	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.3, 4.4, 4.5, 4.8 and 4.9 of Atomoxetine SmPC have information on this safety concern. Sections 2 and 4 of Atomoxetine PIL have information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: DHPC letter on increased blood pressure and increased heart rate

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 Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules.

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

There are no studies required for Atomoxetine 10/18/25/40/60/80/100 mg, hard capsules.