Summary of risk management plan for

Atomoxetin Orion 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg capsules, hard

(atomoxetine hydrochloride)

Orion Corporation

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

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

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

I. The medicine and what it is used for

Atomoxetin Orion is authorised for treatment of attention-deficit and hyperactivity disorder (ADHD) in children over six years of age, in young people, and in adults (see SmPC for the full indication). It contains atomoxetine hydrochloride as the active substance and it is given by mouth.

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

Important risks of Atomoxetin Orion, together with measures to minimise such risks and the proposed studies for learning more about Atomoxetin Orion'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;
- 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 Atomoxetin Orion, 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 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 Orion 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 Atomoxetin Orion. 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 (myocardial ischaemia, tachyarrhythmia, cerebrovascular accident) • QTc prolongation • Aggression/hostility • Seizures
Missing information	• None

II.B Summary of important risks

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

Important identified risk: Increased blood pressure and increased heart rate	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2, 4.3, 4.4, 4.5 and 4.8. PL sections 2, 3 and 4. *In SmPC and PL it is advised that patients who are being considered for treatment with atomoxetine should have a careful history and physical exam to assess for the presence of cardiac disease. Blood pressure and heart rate monitoring should be done before and during the treatment.* Additional risk minimisation measures: Physician's Guide