

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln.**

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

Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln's summary of product characteristics gives essential information to healthcare professionals and patients on how Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln should be used.

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

### **I. The medicine and what it is used for**

Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln is indicated for:

Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme.

It contains atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln as the active substance and it is given orally.

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

Important risks of Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln, together with measures to minimise such risks and learning more about Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln'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 leaflets 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 Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks

sufficient proof of a link with the use of Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln. 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).

<i>List of important risks and missing information</i>	
<b>Important identified risks</b>	None
<b>Important potential risks</b>	None
<b>Missing information</b>	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***

No post authorisation study is planned for this product.

#### **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 AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln.

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

There are no studies required for Atomoxetine AmaroX 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg Hartkapseln.