VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Attention deficit/hyperactivity disorder (ADHD) is a condition which leads patients, especially children, to having trouble with paying attention and staying focused. Patients tend to be too active and not to consider the results of their actions.

ADHD can cause problems in different situations such as at home, at school, at work, or during interactions with other people.

It oftens starts in childhood and can continue until adulthood. Boys/men are more affected with having ADHD than girls/women.

ADHD commonly occurs with other conditions such as learning disabilities, mood-related disorders, or drug and/or alcohol abuse and that also could cause patients to have a difficult personality.

In European countries, approximately 1.9% to 7.0% of children and approximately 1% to 7% of adults have ADHD.

VI.2.2 Summary of treatment benefits

<Product name> contains the active substance atomoxetine and is used to treat attention-deficit and hyperactivity disorder (ADHD). It is used in children over six years of age, adolescents and adults.
Atomoxetine is used as part of a combined treatment of the disease which additionaly requires treatments such as behavioural therapy and counselling.

<Product name> increases the amount of noradrenaline in the brain which helps to control the symptoms of ADHD. Noradrenaline is a naturally produced chemical which increases the attention and decreases the impulsiveness and hyperactivity.

VI.2.3 Unknowns relating to treatment benefits

The use of atomoxetine in patients over 65 years of age has not been systematically evaluated. The safety and efficacy of atomoxetine in children under 6 years of age have not been established. Therefore, <Product name> should not be used in children under 6 years of age.

For atomoxetine clinical data on exposed pregnancies are limited. Such data are insufficient to indicate either an association or a lack of association between atomoxetine and adverse pregnancy and/or lactation outcomes. Atomoxetine should not be used during pregnancy unless the potential benefit justifies the potential risk to the foetus.
Atomoxetine and/or its metabolites were excreted in the milk of rats. It is not known if atomoxetine is excreted in human milk. Because of the lack of data, atomoxetine should be avoided during breast-feeding.

Data on the effects on the ability to drive and use machines are limited. Atomoxetine has a minor influence on the ability to drive and use machines. Atomoxetine has been associated with increased rates of fatigue, somnolence, and dizziness relative to placebo in paediatric and adult patients. Patients should be advised to use caution when driving or operating hazardous machinery until they are reasonably certain that their performance is not affected by atomoxetine.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Thinking About Killing Oneself (Suicidal Ideation)	Thinking about killing oneself affects about 1 to 10 patients in 1,000 who take atomoxetine. Thoughts of killing oneself can vary widely in the number of times they happen and how serious they are. Stopping atomoxetine treatment has been shown to stop thoughts about killing oneself.	The instructions your doctor receives suggest that he or she watch you or ask you questions about thoughts of killing yourself, worsening of ADHD, or unusual changes in behaviour. Patients and those who care for them should also watch for suicidal thoughts or behaviours. If these are seen, notify the doctor immediately.
Damage to the Liver (Hepatic Injury)	Damage to the liver affects less than 1 patient in 10,000 who takes atomoxetine. Liver injury can range from mild to severe. Mild cases of liver injury will most likely have no symptoms. Symptoms of liver injury include tiredness, dark urine, upset stomach, itching, stomach pain, and yellowing of the skin or eyes.	The instructions your doctor receives about prescribing atomoxetine recommend that atomoxetine be stopped in patients with yellowing of the skin or eyes or laboratory tests showing liver damage, and should not be restarted. Patients and those who care for them should also watch for signs of liver damage. If these are seen, notify the doctor immediately.
Increased Blood Pressure and Increased Heart Rate	Increased blood pressure and heart rate affect about 1 patient in 10 who takes atomoxetine. Higher and important increases may occur in more than 1 out of 10 atomoxetine users. Although it is possible that such increases can cause heart rhythms that are not regular or damage to organs, these events do not seem to be associated with atomoxetine use.	The instructions your doctor receives about prescribing atomoxetine recommend that he or she examine you or ask you questions about early symptoms. It is recommended that your blood pressure and heart rate be taken by your doctor before starting atomoxetine, and during treatment after each change in dose for 6 months to see if there are any clinically important increases. Patients and those who care for them should also watch for signs of extremely high blood pressure, such as severe headache, severe anxiety, shortness of breath, nosebleeds, or fast heartbeat. If these are seen, notify the doctor immediately.

Paleness, burning, prickling, or pain of the fingers and/or toes (Peripheral Vascular Instability [Raynaud's phenomenon])	Paleness, burning, prickling, or pain of the fingers and/or toes affects about 1 to 10 patients in 1,000 who take atomoxetine. If this is severe, it could affect blood circulation to the fingers and/or toes causing damage to them.	Your doctor is informed of the possible occurrence of this condition and he/she may examine you or ask you questions about early symptoms. If you have experienced these symptoms in the past, tell your doctor about them. Patients and those who care for them should also be examined for signs of paleness, burning, prickling, or pain in the fingers and toes. If these are seen, notify the doctor immediately.

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
Heart Problems (Cardiovascular and cerebrovasculuar effects [QTc prolongation, myocardial ischaemia, tachyarrhythmia, cerebrovascular accident])	Heart problems affect less than 1 in 10,000 patients who take atomoxetine. The risk of heart problems is considered potential as they may be the result of increased heart rate and/or increased blood pressure. However, large studies have not actually shown that heart problems occur more frequently in patients taking medicines for ADHD, including atomoxetine.
Aggression/Hostility or Unfriendly and Angry Feelings	Aggression and hostility affect about 1 to 10 patients in 1,000 who take atomoxetine. People with aggression or hostility can have temper tantrums or attack people, lie, or destroy property. Aggression and hostility are considered a potential risk because aggressive, unfriendly, and angry feelings occur frequently in patients with ADHD and other psychiatric diseases, regardless of treatment. Studies have not confirmed that taking atomoxetine will make patients be aggressive or hostile. Also, it is not understood how atomoxetine would affect a person's body to lead to aggression or hostility.
Seizure/Convulsion	Convulsions affect less than 1 in 10,000 patients who take atomoxetine. In general, patients with ADHD have convulsions more often than people without ADHD, regardless of treatment. However, large studies have not shown that convulsions occur more frequently in patients taking atomoxetine. Also, there is no understood way that atomoxetine would affect a person's body to lead to convulsions.

Missing information

Risk	What is known
None	None

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable