LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Atomoxetin Medical Valley (atomoxetine hydrochloride)

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Summary Public Assessment Report

Atomoxetin Medical Valley
atomoxetine hydrochloride

Capsule, hard, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg

This is a summary of the public assessment report (PAR) for Atomoxetin Medical Valley. It explains how Atomoxetin Medical Valley was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Atomoxetin Medical Valley.

For practical information about using Atomoxetin Medical Valley, patients should read the package leaflet or contact their doctor or pharmacist.

What is Atomoxetin Medical Valley and what is it used for?
Atomoxetin Medical Valley is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Strattera.

Atomoxetin Medical Valley contains atomoxetine and is used to treat attention-deficit and hyperactivity disorder (ADHD). It is used:
- in children over six years of age
- in adolescents
- in adults

It is used only as a part of the total treatment of the disease which also requires treatments which do not involve medicines, such as counselling and behavioural therapy.

It is not for use as a treatment for ADHD in children under 6 years of age as it is not known if the medicine works or is safe in these people.

In adults, this medicine is used to treat ADHD when the symptoms are very troublesome and affect the individual's work or social life and when the individual has had symptoms of the disease as a child.

How does Atomoxetin Medical Valley work?
This medicine increases the amount of noradrenaline in the brain. This is a chemical that is produced naturally, and increases attention and decreases impulsiveness and hyperactivity in patients with ADHD. This medicine has been prescribed to help control the symptoms of ADHD. This medicine is not a stimulant and is therefore not addictive.

It may take a few weeks after the individual starts the medicine for the symptoms to fully improve.

How is Atomoxetin Medical Valley used?
The pharmaceutical form of Atomoxetin Medical Valley is hard capsules for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Atomoxetin Medical Valley have been shown in studies?
Because Atomoxetin Medical Valley is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Strattera.

What are the possible side effects from Atomoxetin Medical Valley?
Because Atomoxetin Medical Valley is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Atomoxetin Medical Valley approved?
It was concluded that, in accordance with EU requirements, Atomoxetin Medical Valley has been shown to have comparable quality and is considered bioequivalent to the reference medicine Strattera. Therefore, the Swedish Medical Products Agency decided that, as for Strattera, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Atomoxetin Medical Valley?
A risk management plan has been developed to ensure that Atomoxetin Medical Valley is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Atomoxetin Medical Valley, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

There are **additional risk minimisation measures** in place for the originator's product. The originator has distributed educational material as agreed with the CHMP PV Working Party in November 2011. This consists of:
- Physician's guide for assessing and monitoring cardiovascular risk when prescribing atomoxetine
- A checklist for actions to take before prescribing/dispensing or administering atomoxetine
- A checklist for actions to take during monitoring to manage cardiovascular risks with atomoxetine treatment
- Measurement recording chart (to help keep good records of blood pressure and heart rate during atomoxetine treatment)

The MAH is therefore obliged to ensure distribution of the educational material prior to launching the medicinal product onto the market. Distribution methods should be agreed with the national competent authorities.
The aim of the educational material is to reinforce the label recommendations regarding medical history, and comorbidities assessments at baseline for contraindications and values to be monitored and provide support for monitoring heart rate and blood pressure.
The educational material should contain the following key elements:
- Physician's guide for assessing and monitoring cardiovascular risk when prescribing atomoxetine
- A checklist for actions to take before prescribing /dispensing or administering atomoxetine
- A checklist for actions to take during monitoring to manage cardiovascular risks with atomoxetine treatment and measurement recording chart
- Measurement recording chart (to help keep good records of blood pressure and heart rate during atomoxetine treatment)

Other information about Atomoxetin Medical Valley
The full PAR for Atomoxetin Medical Valley can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Atomoxetin Medical Valley

This summary was last updated in 2022-04.