Package leaflet: Information for the user

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

Atomoxetine (as hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What /…/ is and what it is used for
2. What you need to know before you take /…/
3. How to take /…/
4. Possible side effects
5. How to store /…/
6. Contents of the pack and other information

1. What /.../ is and what it is used for

What it is used for
/.../ contains atomoxetine and is used to treat attention-deficit and hyperactivity disorder (ADHD). It is used
- in children over six years of age
- in young people
- 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 drug works or is safe in this age group.

In adults, /.../ is used to treat ADHD when the symptoms are very troublesome and affect your work or social life and when you have had symptoms of the disease as a child.

How it works
/.../ 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 you start the medicine for your symptoms to fully improve.

About ADHD
Children and young people with ADHD find it:
- hard to sit still and
- hard to concentrate.

It is not their fault that they cannot do these things. Many children and young people struggle to do these things. However, with ADHD this can cause problems with everyday life. Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places. ADHD does not affect the intelligence of a child or young person.

Adults with ADHD find it difficult to do all the things that children find difficult; however this may mean they have problems with:
- work
- relationships
- low self esteem
- education

2. What you need to know before you take /…/

Do not take /…/:
- if you are allergic to atomoxetine or any of the other ingredients of this medicine (listed in section 6).
- if you took a medicine known as a monoamine oxidase inhibitor (MAOI), for example phenelzine, in the last two weeks. An MAOI is sometimes used for depression and other mental-health problems; taking /.../ with an MAOI could cause serious side effects or be life-threatening. You also need to wait at least 14 days after you stop taking /.../ before you take an MAOI
- if you have an eye disease called narrow-angle glaucoma (increased pressure in your eye)
- if you have serious problems with your heart which may be affected by an increase in heart rate and/or blood pressure, as this may be an effect of /.../
- if you have serious problems with the blood vessels in your brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm) or narrow or blocked blood vessels
- have a tumour of your adrenal gland (phaeochromocytoma)

Do not take /.../ if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you take /.../. This is because /.../ can make these problems worse.

Warnings and precautions
Both adults and children should be aware of the following warnings and precautions. Talk to your doctor or pharmacist before taking /.../ if you have:
- thoughts about killing yourself or trying to kill yourself.
- problems with your heart (including heart defects) or an increased heartbeat. /.../ can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. /.../ can increase blood pressure.
- low blood pressure. /.../ can cause dizziness or fainting in people with low blood pressure.
- problems with sudden changes in your blood pressure or your heart rate.
- cardiovascular disease or past medical history of stroke.
- liver problems. You may need a lower dose.
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.
- mania (feeling elated or over-excited, which causes unusual behaviour) and agitation.
- aggressive feelings.
- unfriendly and angry (hostility) feelings.

- a history of epilepsy or have had seizures for any other reason. /.../ might lead to an increase in seizure frequency.
- different moods than usual (mood swings) or feel very unhappy.
- hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.

Tell your doctor or pharmacist if any of the above applies to you before starting treatment. This is because /.../ can make these problems worse. Your doctor will want to monitor how the medicine affects you.

Checks that your doctor will make before you start to take /.../
These checks are to decide if /.../ is the correct medicine for you.

Your doctor will measure your
- blood pressure and your heart rate (pulse) before and during the time you take /.../
- your height and weight if you are a child or teenager during the time you take /.../

Your doctor will talk to you about:
- any other medicines you are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have

It is important that you provide as much information as you can. This will help your doctor decide if /.../ is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Other medicines and /…/
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This includes non-prescription medicines. Your doctor will decide if you can take /.../ with your other medicines and in some cases your doctor may need to adjust your dose or increase your dose much more slowly.

Do not take /.../ with medicines called MAOIs (monoamine oxidase inhibitors) used for depression. See section 2 “Do not take /.../”.

If you are taking other medicines, /.../ may affect how well they work or may cause side effects. If you are taking any of the following medicines, check with your doctor or pharmacist before taking /.../:

- medicines that increase blood pressure or are used to control blood pressure
- medicines such as antidepressants, for example imipramine, venlafaxine, mirtazapine, fluoxetine and paroxetine
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- some medicines used to treat mental health conditions
- medicines that are known to increase the risk of seizures
- some medicines that cause /.../ to stay in the body for longer than normal (such as quinidine and terbinafine)
- salbutamol (a medicine to treat asthma) when taken by mouth or injected may make you feel as if your heart is racing, but this will not make your asthma worse

The medicines below may lead to an increased risk of an abnormal rhythm of the heart when taken with /.../:
- medicines used to control the rhythm of the heart
- medicines which change the concentration of salts in the blood

- medicines for malaria prevention and treatment
- some antibiotic medicines (such as erythromycin and moxifloxacin)

If you are not sure about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking /.../.

Pregnancy and breast-feeding
It is not known if this medicine can affect an unborn baby or pass into breast milk.
- This medicine should not be used during pregnancy, unless your doctor has advised you to do so.
- You should either avoid taking this medicine if you are breast-feeding or discontinue breastfeeding.

If you are pregnant or breast-feeding, thinking you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You may feel tired, sleepy or dizzy after taking /.../. You should be careful if you are driving a car or operating heavy machinery until you know how /.../ affects you. If you feel tired, sleepy or dizzy you should not drive or operate machinery.

Important information about the content of the capsules
Do not open /.../ capsules because the contents of the capsule can irritate the eye. If the contents of the capsules come into contact with the eye, the affected eye should be flushed immediately with water, and medical advice obtained. Hands and any other part of the body that may have come into contact with the capsule contents should also be washed as soon as possible.

3. How to take /…/

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. This is usually one or two times a day (morning and late afternoon or early evening)
- Children should not take this medicine without help from an adult
- If you are taking /.../ once a day and experience sleepiness or feel sick, your doctor may change your treatment schedule to twice a day
- The capsules should be swallowed whole, either with or without food
- The capsules should not be opened and the contents inside the capsules should not be removed and taken in any other way
- Taking the medicine at the same time each day may help you remember to take it

Use in children and adolescents

If you are a child or teenager (6 years or older):
Your doctor will tell you how much /.../ you should take and will calculate this according to your weight. He/she will normally start you on a lower dose before increasing the amount of /.../ you need to take according to your body weight.

- Body weight up to 70 kg: a starting total daily dose of 0.5 mg per kg of body weight for a minimum of 7 days. Your doctor may then decide to increase this to the usual maintenance dose of about 1.2 mg per kg of body weight daily.

- Body weight over 70 kg: a starting total daily dose of 40 mg for a minimum of 7 days. Your doctor may then decide to increase this to the usual maintenance dose of 80 mg daily. The maximum daily dose your doctor will prescribe is 100 mg.

Adults
- /.../ should be started at a total daily dose of 40 mg for a minimum of 7 days. Your doctor may then decide to increase this to the usual maintenance dose of 80-100 mg daily. The maximum daily dose your doctor will prescribe is 100 mg.

If you have problems with your liver your doctor may prescribe a lower dose.

If you take more /…/ than you should
Contact your doctor or the nearest hospital casualty department immediately and tell them how many capsules you have taken. The most commonly reported symptoms accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behaviour.

If you forget to take /…/
If you miss a dose, you should take it as soon as possible, but you should not take more than your total daily dose in any 24-hour period. Do not take a double dose to make up for a forgotten dose.

If you stop taking /…/
If you stop taking /.../ there are usually no side effects but your ADHD symptoms may return. You should talk to your doctor first before you stop treatment.

Things your doctor will do when you are on treatment
Your doctor will do some tests
- before you start - to make sure that /.../ is safe and will be of benefit.
- after you start - they will be done at least every 6 months, but possibly more often.

They will also be done when the dose is changed. These tests will include:
- measuring height and weight in children and young people
- measuring blood pressure and heart rate
- checking whether you have any problems or if side effects have got worse while taking /.../

Long-term treatment
/.../ does not need to be taken forever. If you take /.../ for more than a year, your doctor will review your treatment, to see if the medicine is still needed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Although some people get side effects most people find that /.../ helps them. Your doctor will talk to you about these side effects.

Some side effects could be serious**. If you have any of the side effects below, see a doctor straight away.**

Uncommon (may affect up to 1 in 100 people)

- feeling or having a very fast heartbeat, abnormal rhythms of the heart
- thinking about or feeling like killing yourself
- feeling aggressive
- feeling unfriendly and angry (hostility)
- mood swings or mood changes
- serious allergic reaction with symptoms of

  - swelling of the face and throat
  - difficulty breathing
  - hives (small raised, itchy patches of skin)
- seizures
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious

Children and adolescents aged under 18 have an increased risk of side effects such as:
- thinking about or feeling like killing yourself (may affect up to 1 in 100 people)
- mood swings or mood changes (may affect up to 1 in 10 people)

Adults have a reduced risk (may affect up to 1 in 1,000 people**) of side effects such as:**
- seizures
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious

Rare (may affect up to 1 in 1,000 people**)**
- liver injury

You should stop taking /.../ and call your doctor immediately if you have any of the following:
- dark urine
- yellow skin or yellow eyes
- tummy pain which is sore when you press it (tenderness) on the right side just below your ribs
- a feeling of sickness (nausea) that is unexplained
- tiredness
- itching
- feeling that you are coming down with flu

Other side effects reported include the following. If they get serious, tell your doctor or pharmacist.

Children and adolescents over 6 years
Very Common (may affect more than 1 in 10 people)
- headache
- pain in the stomach
- decreased appetite (not feeling hungry)
- feeling or being sick
- sleepiness
- increased blood pressure
- increased heart rate (pulse)

These effects may disappear after a while in most patients.

Common (may affect up to 1 in 10 people)
- being irritable or agitated
- problems sleeping including waking early
- depression
- feeling sad or hopeless
- feeling anxious
- tics
- large pupils (the dark centre of the eye)
- dizziness
- constipation
- loss of appetite
- upset stomach, indigestion

- swollen, reddened and itchy skin
- rash
- feeling lazy (lethargy)
- chest pain
- tiredness
- weight loss

Uncommon side effects (may affect up to 1 in 100 people)
- fainting
- tremor
- migraine
- blurred vision
- abnormal skin sensation, such as burning, prickling, itching, or tingling
- tingling or numbness in the hands or feet
- seizure (fits)
- feeling or having a very fast heartbeat (QT prolongation)
- shortness of breath
- increased sweating
- itchy skin
- lack of strength or energy

Rare (may affect up to 1 in 1,000 people)
- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)
- problems going to the toilet such as frequent or hesitant urinating, pain on urinating
- prolonged and painful erections
- groin pain in males

Adults
Very Common (may affect more than 1 in 10 people)
- feeling sick
- dry mouth
- headache
- decreased appetite (not feeling hungry)
- problems getting to sleep, staying asleep and waking early
- increased blood pressure
- increased heart rate (pulse)

Common (may affect up to 1 in 10 people)
- feeling agitated
- decreased interest in sex
- sleep disturbance
- depression
- feeling sad or hopeless
- feeling anxious
- dizziness
- an abnormal taste or change in taste that will not go away
- tremor
- tingling or numbness in the hands or feet
- sleepiness, drowsy, feeling tired
- constipation
- stomach ache
- indigestion
- wind (flatulence)
- being sick

- hot flush or flushing
- feeling or having a very fast heartbeat
- swollen, reddened and itchy skin
- increased sweating
- rash
- problems going to the toilet such as not be able to urinate, frequent or hesitant urinating, pain on urinating
- inflammation of the prostate gland (prostatitis)
- groin pain in men
- failure to obtain an erection
- retarded orgasm
- difficulty maintaining an erection
- menstrual cramps
- lack of strength or energy
- tiredness
- feeling lazy (lethargy)
- chills
- feeling, irritable, jittery
- feeling thirsty
- weight loss

Uncommon (may affect up to 1 in 100 people)
- restlessness
- tics
- fainting
- migraine
- blurred vision
- heart rhythm abnormal (QT prolongation)
- feeling cold in fingers and toes
- chest pain
- shortness of breath
- raised red itchy rashes (hives)
- muscle spasms
- an urge to urinate
- abnormal or absence of orgasm
- irregular menstruation
- ejaculation failure

Rare (may affect up to 1 in 1,000 people)
- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)
- prolonged and painful erections

Effects on growth
Some children experience reduced growth (weight and height) when they start taking /.../. However, with long-term treatment, children recover to the weight and height for their age range. Your doctor will watch your child's height and weight over time. If your child is not growing or gaining weight as expected, your doctor may change your child's dose or decide to stop /.../ temporarily.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /…/

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Tablet container:
Use within 6 months after first opening.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What /…/contains

- The active substance is atomoxetine hydrochloride. Each hard capsule contains atomoxetine hydrochloride equivalent to either 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg of atomoxetine.
- The other ingredients are:
  Capsule content: co-processed maize starch (consisting of maize starch and pregelatinised starch), dimethicone 350 cs, sodium starch glycolate (type A).
  Capsule shell: gelatin, titanium dioxide (E171), black ink (which contains shellac, propylene glycol, ammonia solution, black iron oxide (E172) and potassium hydroxide) and colourants*.

* The colourants are:
10 mg: No additional colourant.
18 mg: Yellow iron oxide (E172)
25 mg: and 40 mg: Indigotine (E132) and black iron oxide (E172)
60 mg: Indigotine (E132), black iron oxide (E172) and yellow iron oxide (E172)
80 mg and 100 mg: Yellow iron oxide (E172) and red iron oxide (E172)

What /…/ looks like and contents of the pack

10 mg: Opaque white hard capsules, size 4 (14.3 mm x 5.31 mm), imprinted with “A910” in black ink.
18 mg: Opaque gold (cap) and opaque white (body) hard capsules, size 3 (15.9 mm x 5.82 mm), imprinted with “A918” in black ink.
25 mg: Opaque blue (cap) and opaque white (body) hard capsules, size 3 (15.9 mm x 5.82 mm), imprinted with “A925” in black ink.
40 mg: Opaque blue hard capsules, size 2 (18 mm x 6.35 mm), imprinted with “A940” in black ink.
60 mg: Opaque blue (cap) and opaque gold (body) hard capsules, size 2 (18 mm x 6.35 mm), imprinted with “A960” in black ink.
80 mg: Opaque brown (cap) and opaque white (body) hard capsules, size 1 (19.4 mm x 6.91 mm), imprinted with “A980” in black ink.
100 mg: Opaque brown hard capsules, size 0 (21.7 mm x 7.65 mm), imprinted with “A900” in black ink.

/.../ is available in blister packs of 7 (10 mg, 18 mg, 25 mg & 40 mg strengths), 28, 30, 56 and 60 capsules.
/…/ is also available in tablet containers of 28 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>

Other sources of information

<Detailed information on this medicine is available on the website of {MS/Agency}>