

## Package leaflet: Information for the user

[Invented name] 10 mg hard capsules  
[Invented name] 18 mg hard capsules  
[Invented name] 25 mg hard capsules  
[Invented name] 40 mg hard capsules  
[Invented name] 60 mg hard capsules  
[Invented name] 80 mg hard capsules  
[Invented name] 100 mg hard capsules

Atomoxetine

**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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

### 1. What [Invented name] is and what it is used for

#### What it is used for

[Invented 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
- 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.

In adults, this medicine 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

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 you start the medicine for your symptoms to fully improve.

#### About ADHD

Children and adolescents 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 adolescents struggle to do these things. However, with ADHD this can cause problems with everyday life. Children and adolescents

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 adolescent.

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 [Invented name]**

### **Do not take [Invented name] if you:**

- are allergic to atomoxetine or any of the other ingredients of this medicine (listed in section 6).
- 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 [Invented name] 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 this medicine before you take an MAOI.
- have an eye disease called narrow-angle glaucoma (increased pressure in your eye).
- 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 [Invented name].
- 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 [Invented name] if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you take this medicine. This is because this medicine can make these problems worse.

### **Warnings and precautions**

Both adult and children should be aware of the following warnings and precautions. Talk to your doctor or pharmacist before taking [Invented name] if you have:

- thoughts about killing yourself or trying to kill yourself.
- problems with your heart (including heart defects) or an increased heartbeat. [Invented name] can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. [Invented name] can increase blood pressure.
- low blood pressure. [Invented name] 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. [Invented name] 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 [Invented name] 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 [Invented name]**

These checks are to decide if [Invented name] 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 [Invented name]
- your height and weight if you are a child or teenager during the time you take [Invented name]

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 [Invented name] is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

### **Important information about the content of the capsules**

Do not open [Invented name] 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.

### **Children**

[Invented name] 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.

### **Other medicines and [Invented name]**

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

If you are taking other medicines, [Invented name] 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 [Invented name]:

- 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 get 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 [Invented name] 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 [Invented name]:

- 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 [Invented name].

### **Pregnancy and breast-feeding**

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

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 breast-feeding.

### **Driving and using machines**

You may feel tired, sleepy or dizzy after taking [Invented name]. You should be careful if you are driving a car or operating machinery until you know how [Invented name] affects you. If you feel tired, sleepy or dizzy you should not drive or operate machinery.

## **3. How to take [Invented name]**

- 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 the help from an adult.
- If you are taking [Invented name] once a day and experience sleepiness or feel sick, your doctor may change your treatment schedule to twice a day.
- Oral use.
- 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.

### **How much to take**

#### **If you are a child or adolescent (6 years or older):**

Your doctor will tell you how much [Invented name] you should take and will calculate this according to your weight. Your doctor will normally start you on a lower dose before increasing the amount of [Invented name] 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**

- [Invented name] 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 mg-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.

## **Things your doctor will do when you are on treatment**

### **Your doctor will do some tests**

- before you start - to make sure that [Invented name] 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 adolescents
- measuring blood pressure and heart rate
- checking whether you have any problems or if side effects have got worse while taking [Invented name].

### **Long-term treatment**

[Invented name] does not need to be taken for ever. If you take [Invented name] for more than a year, your doctor will review your treatment, to see if the medicine is still needed.

**If you take more [Invented name] 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 [Invented name]**

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 [Invented name]**

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

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. Your doctor will talk to you about these side effects.

### **You should stop taking [Invented name] 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

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

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

- liver injury

**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

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

<b>Very common side effects (may affect more than 1 in 10 people)</b>	
<b>CHILDREN and ADOLESCENTS over 6 years</b>	<b>ADULTS</b>
<ul style="list-style-type: none"> <li>- headache</li> <li>- pain in the stomach</li> <li>- decreased appetite (not feeling hungry)</li> <li>- feeling or being sick</li> <li>- sleepiness</li> <li>- increased blood pressure</li> <li>- increased heart rate (pulse)</li> </ul> <p>These effects may disappear after a while in most patients.</p>	<ul style="list-style-type: none"> <li>- feeling sick</li> <li>- dry mouth</li> <li>- headache</li> <li>- decreased appetite (not feeling hungry)</li> <li>- problems getting to sleep, staying asleep and waking early</li> <li>- increased blood pressure</li> <li>- increased heart rate (pulse)</li> </ul>

<b>Common side effects (may affect up to 1 in 10 people)</b>	
<b>CHILDREN and ADOLESCENTS over 6 years</b>	<b>ADULTS</b>
<ul style="list-style-type: none"> <li>- being irritable or agitated</li> <li>- problems sleeping including waking early</li> <li>- depression</li> <li>- feeling sad or hopeless</li> <li>- feeling anxious</li> <li>- tics</li> <li>- large pupils (the dark centre of the eye)</li> <li>- dizziness</li> <li>- constipation</li> <li>- loss of appetite</li> <li>- upset stomach, indigestion</li> <li>- swollen, reddened and itchy skin</li> <li>- rash</li> <li>- feeling lazy (lethargy)</li> <li>- chest pain</li> <li>- tiredness</li> <li>- weight loss</li> </ul>	<ul style="list-style-type: none"> <li>- feeling agitated</li> <li>- decreased interest in sex</li> <li>- sleep disturbance</li> <li>- depression</li> <li>- feeling sad or hopeless</li> <li>- feeling anxious</li> <li>- dizziness</li> <li>- an abnormal taste or change in taste that will not go away</li> <li>- tremor</li> <li>- tingling or numbness in the hands or feet</li> <li>- sleepiness, drowsy, feeling tired</li> <li>- constipation</li> <li>- stomach ache</li> <li>- indigestion</li> <li>- wind (flatulence)</li> <li>- being sick</li> </ul>

	<ul style="list-style-type: none"> <li>- hot flush or flushing</li> <li>- feeling or having a very fast heartbeat</li> <li>- swollen, reddened and itchy skin</li> <li>- increased sweating</li> <li>- rash</li> <li>- problems going to the toilet such as not be able to urinate, frequent or hesitant urinating, pain on urinating</li> <li>- inflammation of the prostate gland (prostatitis)</li> <li>- groin pain in men</li> <li>- failure to obtain an erection</li> <li>- retarded orgasm</li> <li>- difficulty maintaining an erection</li> <li>- menstrual cramps</li> <li>- lack of strength or energy</li> <li>- tiredness</li> <li>- feeling lazy (lethargy)</li> <li>- chills</li> <li>- feeling, irritable, jittery</li> <li>- feeling thirsty</li> <li>- weight loss</li> </ul>
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<b>Uncommon side effects (may affect up to 1 in 100 people)</b>	
<b>CHILDREN and ADOLESCENTS over 6 years</b>	<b>ADULTS</b>
<ul style="list-style-type: none"> <li>- fainting</li> <li>- tremor</li> <li>- migraine</li> <li>- blurred vision</li> <li>- abnormal skin sensation, such as burning, prickling, itching, or tingling</li> <li>- tingling or numbness in the hands or feet</li> <li>- seizure (fits)</li> <li>- feeling or having a very fast heartbeat (QT prolongation)</li> <li>- shortness of breath</li> <li>- increased sweating</li> <li>- itchy skin</li> <li>- lack of strength or energy</li> </ul>	<ul style="list-style-type: none"> <li>- restlessness</li> <li>- tics</li> <li>- fainting</li> <li>- migraine</li> <li>- blurred vision</li> <li>- heart rhythm abnormal (QT prolongation)</li> <li>- feeling cold in fingers and toes</li> <li>- chest pain</li> <li>- shortness of breath</li> <li>- raised red itchy rashes (hives)</li> <li>- muscle spasms</li> <li>- an urge to urinate</li> <li>- abnormal or absence of orgasm</li> <li>- irregular menstruation</li> <li>- ejaculation failure</li> </ul>

<b>Rare side effects (may affect up to 1 in 1,000 people)</b>	
<b>CHILDREN and ADOLESCENTS over 6 years</b>	<b>ADULTS</b>
<ul style="list-style-type: none"> <li>- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)</li> <li>- problems going to the toilet such as frequent or hesitant urinating, pain on urinating</li> <li>- prolonged and painful erections</li> <li>- groin pain in males</li> </ul>	<ul style="list-style-type: none"> <li>- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)</li> <li>- prolonged and painful erections</li> </ul>

**Effects on growth**

Some children experience reduced growth (weight and height) when they start taking [Invented name]. 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 [Invented name] 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 [Invented name]**

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.

This medicine does not require any special storage conditions.

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 [Invented name] contains**

- The active substance is Atomoxetine.
  
- [Invented name] 10 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 10 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.  
*Capsule shell:* Gelatin, Sodium Lauryl Sulfate (E487), Titanium dioxide (E171)
  
- [Invented name] 18 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 18 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.  
*Capsule shell:* Gelatin, Sodium Laurilsulfate (E487), Titanium dioxide (E171), iron oxide yellow (E172)
  
- [Invented name] 25 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 25 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.  
*Capsule shell:* Gelatin, Sodium Laurilsulfate (E487), Titanium dioxide (E171), indigo carmine (E132)
  
- [Invented name] 40 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 40 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

*Capsule shell:* Gelatin, Sodium Laurilsulfate (E487), Titanium dioxide (E171), indigo carmine (E132)

- [Invented name] 60 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 60 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.  
*Capsule shell:* Gelatin, Sodium Laurilsulfate (E487), Titanium dioxide (E171), indigo carmine (E132), iron oxide yellow (E172)
- [Invented name] 80 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 80 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.  
*Capsule shell:* Gelatin, Sodium Laurilsulfate (E487), Titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)
- [Invented name] 100 mg hard capsules  
Each hard capsule contains atomoxetine hydrochloride equivalent to 100 mg atomoxetine.
- The other ingredients are  
*Capsule content:* Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.  
*Capsule shell:* Gelatin, Sodium Laurilsulfate (E487), Titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)
- Printing ink (black) consisting of: Shellac Glaze-45% (20% Esterified), Iron Oxide Black (E172), Propylene Glycol

#### **What [Invented name] looks like and contents of the pack**

- [Invented name] 10 mg hard capsules  
White powder in a hard gelatin capsule of size No 3 (length of  $15.7 \pm 0.4$  mm), opaque white cap imprinted in black ink with '10' and opaque white body imprinted in black ink with 'mg'.
- [Invented name] 18 mg hard capsules  
White powder in a hard gelatin capsule of size No 3 (length of  $15.7 \pm 0.4$  mm), opaque rich yellow cap imprinted in black ink with '18' and opaque white body imprinted in black ink with 'mg'.
- [Invented name] 25 mg hard capsules  
White powder in a hard gelatin capsule of size No 3 (length of  $15.7 \pm 0.4$  mm), opaque blue cap imprinted in black ink with '25' and opaque white body imprinted in black ink with 'mg'.
- [Invented name] 40 mg hard capsules  
White powder in a hard gelatin capsule of size No 3 (length of  $15.7 \pm 0.4$  mm), opaque blue cap imprinted in black ink with '40' and opaque blue body imprinted in black ink with 'mg'.
- [Invented name] 60 mg hard capsules  
White powder in a hard gelatin capsule of size No 2 (length of  $17.6 \pm 0.4$  mm), opaque blue cap imprinted in black ink with '60' and opaque rich yellow body imprinted in black ink with 'mg'.
- [Invented name] 80 mg hard capsules  
White powder in a hard gelatin capsule of size No 2 (length of  $17.6 \pm 0.4$  mm), opaque brown cap imprinted in black ink with '80' and opaque white body imprinted in black ink with 'mg'.
- [Invented name] 100 mg hard capsules  
White powder in a hard gelatin capsule of size No 1 (length of  $19.1 \pm 0.4$  mm), opaque brown cap imprinted in black ink with '100' and opaque brown body imprinted in black ink with 'mg'.

[Invented name] is supplied in blisters in a cardboard box.

Pack sizes: 7, 28, 50, 56, 60 and 100 hard capsules

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

<[To be completed nationally]>

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

Germany	Atomoxetin Accord
Czech Republic	Atomoxetine Accord
Denmark	Atomoxetine Accord
Spain	Atomben
Finland	Atomoxetine Accord
Ireland	Atomoxetine Accord
Netherlands	Atomoxetine Accord
Norway	Atomoxetine Accord
Poland	Atomoxetine Accord
Romania	Atomoxetină Accord
Sweden	Atomoxetine Accord
Slovenia	Atomoksetin Accord
United Kingdom	Atomoxetine 10 mg capsule, hard Atomoxetine 18 mg capsule, hard Atomoxetine 25 mg capsule, hard Atomoxetine 40 mg capsule, hard Atomoxetine 60 mg capsule, hard Atomoxetine 80 mg capsule, hard Atomoxetine 100 mg capsule, hard

**This leaflet was last revised in**