

Atomoxetine 10 mg hard capsules

Atomoxetine 18 mg hard capsules

Atomoxetine 25 mg hard capsules

Atomoxetine 40 mg hard capsules

Atomoxetine 60 mg hard capsules

Atomoxetine 80 mg hard capsules

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

1. What Atomoxetine is and what it is used for

What Atomoxetine is used for

Atomoxetine 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 Atomoxetine 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.

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 Atomoxetine

Atomoxetine

Do not take Atomoxetine 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 Atomoxetine 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 Atomoxetine.
- 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 Atomoxetine 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 Atomoxetine if you have:

- thoughts about killing yourself or trying to kill yourself.
- problems with your heart (including heart defects) or an increased heartbeat. Atomoxetine can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. Atomoxetine can increase blood pressure.
- low blood pressure. Atomoxetine 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. Atomoxetine 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 Atomoxetine can make these problems worse. Your doctor will want to monitor how the medicine affects you.

Treatment with Atomoxetine may make you feel aggressive, hostile or violent; or aggravate these symptoms if they were present before treatment. It may also cause you to have unusual changes in behaviour or mood (including physical assault, threatening behaviour and thoughts of harming others). If you or your family and/or friends notice any of these reactions, talk to your doctor or pharmacist right away.

Serotonin syndrome:

Serotonin syndrome is a potentially life-threatening condition which may occur when taking Atomoxetine in combination with some other medicines (see section 2 "Other medicines and Atomoxetine"). Signs and symptoms of serotonin syndrome may include a combination of the following: confusion, restlessness, incoordination and rigidity, hallucinations, coma, fast heart beat, increased body temperature, fast changes in blood pressure, sweating, flushing, tremor, overactive reflexes, nausea, vomiting, and diarrhoea. Contact a doctor or go to your nearest emergency department immediately if you think serotonin syndrome is happening to you.

Checks that your doctor will make before you start to take Atomoxetine

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

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

Things your doctor will do when you are on treatment

Your doctor will do some tests

- before you start - to make sure that Atomoxetine 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 Atomoxetine.

Important information about the content of the capsules

Do not open Atomoxetine 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.

Other medicines and Atomoxetine

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 Atomoxetine 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 Atomoxetine with medicines called MAOIs (monoamine oxidase inhibitors) used for depression. See section 2 "Do not take Atomoxetine".

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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.

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 (uncommon - may affect up to 1 in 100 people)
- mood swings or mood changes (common - may affect up to 1 in 10 people)

Adults have a reduced risk (rare - 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

Very common side effects (may affect more than 1 in 10 people)	
CHILDREN and ADOLESCENTS over 6 years	ADULTS
<ul style="list-style-type: none"> - headache - pain in the stomach - decreased appetite (not feeling hungry) - feeling or being sick - sleepiness - increased blood pressure - increased heart rate (pulse) <p>These effects may disappear after a while in most patients.</p>	<ul style="list-style-type: none"> - 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 side effects (may affect up to 1 in 10 people)	
CHILDREN and ADOLESCENTS over 6 years	ADULTS
<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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 side effects (may affect up to 1 in 100 people)	
CHILDREN and ADOLESCENTS over 6 years	ADULTS
<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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 side effects (may affect up to 1 in 1,000 people)	
CHILDREN and ADOLESCENTS over 6 years	ADULTS
<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease) - prolonged and painful erections

Not known (cannot be estimated from the available data)	
CHILDREN and ADOLESCENTS over 6 years	ADULTS
<ul style="list-style-type: none"> - involuntary teeth grinding (bruxism). 	

things that are not true or being suspicious

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

- liver injury

You should stop taking Atomoxetine 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. Effects on growth

Some children experience reduced growth (weight and height) when they start taking Atomoxetine. 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 Atomoxetine temporarily.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Atomoxetine

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 Atomoxetine contains

- The active substance is Atomoxetine.

- Atomoxetine 10 mg hard capsules
Each hard capsule contains 10 mg atomoxetine as 11.43 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171)

- Atomoxetine 18 mg hard capsules
Each hard capsule contains 18 mg atomoxetine as 20.57 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171), iron oxide yellow (E172)

- Atomoxetine 25 mg hard capsules
Each hard capsule contains 25 mg atomoxetine as 28.57 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171), indigo carmine (E132)

- Atomoxetine 40 mg hard capsules
Each hard capsule contains 40 mg atomoxetine as 45.71 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171), indigo carmine (E132)

- Atomoxetine 60 mg hard capsules
Each hard capsule contains 60 mg atomoxetine as 68.57 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171), indigo carmine (E132), iron oxide yellow (E172)

- Atomoxetine 80 mg hard capsules
Each hard capsule contains 80 mg atomoxetine as 91.42 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

- Atomoxetine 100 mg hard capsules
Each hard capsule contains 100 mg atomoxetine as 114.28 mg atomoxetine hydrochloride.
- The other ingredients are
Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone (350).
Capsule shell: Gelatin, Sodium Lauryl Sulfate, Titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

- Printing ink (black) consisting of: Shellac Glaze-45% (20% Esterified) in Ethanol, Iron Oxide Black (E172), Propylene Glycol

What Atomoxetine looks like and contents of the pack

Atomoxetine 10 mg hard capsules

hard gelatin capsule of size No 3 (length of 15.7±0.4 mm), opaque white cap imprinted in black ink with '10' and opaque white body imprinted in black ink with 'mg', containing white powder.

Atomoxetine 18 mg hard capsules

hard gelatin capsule of size No 3 (length of 15.7±0.4 mm), opaque rich yellow cap imprinted in black ink with '18' and opaque white body imprinted in black ink with 'mg', containing white powder.

Atomoxetine 25 mg hard capsules

hard gelatin capsule of size No 3 (length of 15.7±0.4 mm), opaque blue cap imprinted in black ink with '25' and opaque white body imprinted in black ink with 'mg', containing white powder.

Atomoxetine 40 mg hard capsules

hard gelatin capsule of size No 3 (length of 15.7±0.4 mm), opaque blue cap imprinted in black ink with '40' and opaque blue body imprinted in black ink with 'mg', containing white powder.

Atomoxetine 60 mg hard capsules

hard gelatin capsule of size No 2 (length of 17.6±0.4 mm), opaque blue cap imprinted in black ink with '60' and opaque rich yellow body imprinted in black ink with 'mg', containing white powder.

Atomoxetine 80 mg hard capsules

hard gelatin capsule of size No 2 (length of 17.6±0.4 mm), opaque brown cap imprinted in black ink with '80' and opaque white body imprinted in black ink with 'mg', containing white powder.

Atomoxetine 100 mg hard capsules

hard gelatin capsule of size No 1 (length of 19.1 ± 0.4 mm), opaque brown cap imprinted in black ink with '100' and opaque brown body imprinted in black ink with 'mg', containing white powder.

Atomoxetine is supplied in blisters in a cardboard box.

Pack sizes:

Atomoxetine neuraxpharm 10 mg, 18 mg, 100 mg: 7, 14, 28 and 56 hard capsules

Atomoxetine neuraxpharm 25 mg, 40 mg, 60 mg, 80 mg: 7, 14, 28, 56 and 98 hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Neuraxpharm UK Limited
Suite 2, Arlington Flex, Third Floor
Building 1420, Arlington Business Park
Theale, Reading,
Berkshire RG7 4SA
United Kingdom

Manufacturer(s)

Pharmathen SA, Dervenakion 6, Pallini 15351, Attiki, Greece
or Pharmathen International SA, Industrial Park Sapes, Rodopi Prefecture, Block no 5, Rodopi 69300, Greece
or Pharmadox Healthcare Ltd, KW20A Kordin Industrial Park, Paola PLA 3000, Malta
or neuraxpharm Arzneimittel GmbH, Elisabeth-Selbert-Str. 23, 40764 Langenfeld, Germany

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

Germany: Atomoxetin-neuraxpharm 10 mg Hartkapseln
Atomoxetin-neuraxpharm 18 mg Hartkapseln
Atomoxetin-neuraxpharm 25 mg Hartkapseln
Atomoxetin-neuraxpharm 40 mg Hartkapseln
Atomoxetin-neuraxpharm 60 mg Hartkapseln
Atomoxetin-neuraxpharm 80 mg Hartkapseln
Atomoxetin-neuraxpharm 100 mg Hartkapseln

Poland: Atomoxetin NeuroPharma

United Kingdom: Atomoxetin neuraxpharm 10 mg hard capsules
Atomoxetin neuraxpharm 18 mg hard capsules
Atomoxetin neuraxpharm 25 mg hard capsules
Atomoxetin neuraxpharm 40 mg hard capsules
Atomoxetin neuraxpharm 60 mg hard capsules
Atomoxetin neuraxpharm 80 mg hard capsules
Atomoxetin neuraxpharm 100 mg hard capsules

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