

- 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 Atomoxetine

Long-term treatment

Atomoxetine does not need to be taken for ever. If you take Atomoxetine 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 Atomoxetine 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 young adults 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

Rarely (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.

| Very common side effects (may affect more than 1 in 10 people) | |
|--|--|
| CHILDREN and YOUNG PEOPLE 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 YOUNG PEOPLE 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 YOUNG PEOPLE 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 YOUNG PEOPLE 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 |

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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.

This medicine does not require any special storage conditions.

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

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

- The active substance is Atomoxetine hydrochloride.

Each hard capsule contains atomoxetine hydrochloride equivalent to 10 mg of atomoxetine. Each hard capsule contains atomoxetine hydrochloride equivalent to 18 mg of atomoxetine. Each hard capsule contains atomoxetine hydrochloride equivalent to 25 mg of atomoxetine. Each hard capsule contains atomoxetine hydrochloride equivalent to 40 mg of atomoxetine. Each hard capsule contains atomoxetine hydrochloride equivalent to 60 mg of atomoxetine. Each hard capsule contains atomoxetine hydrochloride equivalent to 80 mg of atomoxetine. Each hard capsule contains atomoxetine hydrochloride equivalent to 100 mg of atomoxetine.

- The other ingredients are

The capsules contain: Starch, pregelatinised (Maize Starch), Simethicone Emulsion

In Cap: Titanium Dioxide (E171), Sodium Lauryl Sulfate, Iron oxide Yellow (E172) (For 18 mg, 80 mg & 100 mg), FD&C Blue 2 (E132) (for 25 mg, 40 mg & 60 mg), Iron oxide Red (E172) (for 80 mg & 100 mg), Gelatin

In Body: Titanium Dioxide (E171), Sodium Lauryl Sulfate, FD&C Blue 2 (E132) (for 40 mg only), Iron oxide Yellow (E172) (for 60 mg & 100 mg), Iron oxide Red (E172) (for 100 mg only), Gelatin

Printing ink (Black): Shellac (E904), Black iron oxide (E172)

What Atomoxetine looks like and contents of the pack

Capsule, Hard.

Atomoxetine 10mg hard capsules:

Off-white opaque / off-white opaque, size '5' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on off-white opaque cap and '10' on off-white opaque body with black ink.

Atomoxetine 18mg hard capsules:

Golden opaque/off-white opaque, size '4' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on golden opaque cap and '18' on off-white opaque body with black ink.

Atomoxetine 25mg hard capsules:

Blue opaque / off-white opaque, size '4' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on blue opaque cap and '25' on off-white opaque body with black ink.

Atomoxetine 40mg hard capsules:

Blue opaque / Blue opaque, size '2' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on blue opaque cap and '40' on blue opaque body with black ink.

Atomoxetine 60mg hard capsules:

Blue opaque / Golden opaque, size '1' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on blue opaque cap and '60' on golden opaque body with black ink.

Atomoxetine 80mg hard capsules:

Brown opaque / off-white opaque, size '0' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on brown opaque cap and '80' on off-white opaque body with black ink.

Atomoxetine 100mg hard capsules:

Brown opaque / Brown opaque, size '0EL' hard gelatin capsules filled with white to off-white powder and imprinted with 'AT' on brown opaque cap and '100' on brown opaque body with black ink.

Atomoxetine capsules are available in blister packs.

Pack sizes:

Blister packs: 7 and 28 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000, Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park, West End Road,
Ruislip HA4 6QD, United Kingdom

or

Generis Farmacêutica, S.A.
Rua Joao de Deus, n. o 19,
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Amadora, Portugal

This leaflet was last revised in 11/2022.

The package information leaflet in formats such as Braille, audio, cd-rom or large print is made available on request from patients' organisations.

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- Take your medicine at the same time each day may help you remember to take it.
- Do not stop taking the medicine without talking to your doctor first.

Possible side effects

Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult you trust straight away. They can then talk to your doctor. The main things that could affect you are:

- Your heart beating faster than usual
- Being very depressed and unhappy or wanting to hurt yourself
- Feeling aggressive
- Being very unhappy or having different moods than usual (mood swings)
- Showing signs of an allergic reaction such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- Having fits (seizures)
- Seeing, feeling, or hearing things that other people do not
- Liver injury: tummy pain which is sore when you press it (tenderness) on the right side just below your ribs

As the medicine can make you feel sleepy, it is important not to do outdoor sports like riding a horse or bike, swimming or climbing trees. You could hurt yourself and others.

If you feel unwell in any way while you are taking your medicine please tell an adult you trust straight away.

Other things to remember

- Make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.
- The medicine is only for you - do not let anyone else have it. It may help you, but it could hurt someone else.
- If you forget to take your medicine don't take two capsules the next time. Just take one capsule at the next normal time.
- If you do take too much medicine, tell your mum, dad or carer right away.
- It is important not to take too much medicine or you will get ill.
- Don't stop taking your medicine until your doctor says it's OK

Who should I ask if there is anything I don't understand?

Your mum, dad, carer, your doctor, nurse or pharmacist will be able to help you.

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