Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

Atomoxetine P1540056

Atomoxetine P1540056

Package leaflet: Information for the user

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 hydrochloride

Important things you need to know about your medicine

This medicine is used to treat ADHD
- The full name for ADHD is 'Attention Deficit Hyperactivity Disorder'.
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other help for ADHD as well as this medicine.

Read Section 1 for more information.

Before you take this medicine, talk to your doctor if you:
- have mental health problems
- have a problem with your heart or blood circulation
- have serious problems with the blood vessels in your brain such as a stroke

Read Section 2 for more information.

While taking this medicine:
- See your doctor regularly. This is because your doctor will want to check how the medicine is working.
- Do not stop taking the medicine without first talking to your doctor.
- Your doctor may stop your medicine to see if it is still needed, if you take it for more than a year.
- The most common side effects in children and young people are: headache, stomach ache, not feeling hungry, feeling or being sick, feeling sleepy, increased blood pressure, increased heart rate (pulse).
- The most common side effects in adults are: feeling sick, dry mouth, headache, not feeling hungry, not being able to sleep, increased blood pressure, increased heart rate (pulse).

Read Sections 3 and 4 for more information.

Talk to your doctor straight away if any of the following happen:
- your mood and how you feel changes
- you feel any problems with your heart e.g. a fast or unusual heartbeat rhythm

Read Section 2 and 4 for more information.

The rest of this leaflet includes more detail and other important information on the safe and effective use of this medicine.

- 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.

The leaflet has been written in sections:
Sections 1 to 6 are for parents and carers (sometimes called 'your guardians').
The last section is a special section for a child or young person to read.
However, all sections are written as though the child or young person taking the medicine is reading them.

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 it is used for
Atomoxetine 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 these people.

In adults, Atomoxetine 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
Atomoxetine 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 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 Atomoxetine 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 Atomoxetine. This is because Atomoxetine 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.

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.

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.

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.

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.

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".

If you are taking other medicines, Atomoxetine 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 Atomoxetine:
- 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 Atomoxetine 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

Atomoxetine may affect or be affected by other medicines. These include:
- some antidepressants, opioids as tramadol, and medicines used to treat migraine called triptans. These medicines may interact with Atomoxetine and can lead to serotonin syndrome, a potentially life-threatening condition. (See section 2, Warnings and Precautions, Serotonin Syndrome).

The medicines below may lead to an increased risk of an abnormal rhythm of the heart when taken with Atomoxetine:
- 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 Atomoxetine.

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 breastfeeding or discontinue breastfeeding.

If you are:
- pregnant or breast feeding,
- thinking that you may be pregnant or are planning to have a baby,
- planning to breastfeed your 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 Atomoxetine. You should be careful if you are driving a car or operating machinery until you know how Atomoxetine affects you. If you feel tired, sleepy or dizzy you should not drive or operate machinery.

This medicine contains 0.0022 mg benzoic acid in each 10 mg hard Capsule.
This medicine contains 0.0040 mg benzoic acid in each 18 mg hard Capsule.
This medicine contains 0.0056 mg benzoic acid in each 25 mg hard Capsule.
This medicine contains 0.0090 mg benzoic acid in each 40 mg hard Capsule.
This medicine contains 0.0135 mg benzoic acid in each 60 mg hard Capsule.
This medicine contains 0.0180 mg benzoic acid in each 80 mg hard Capsule.
This medicine contains 0.0225 mg benzoic acid in each 100 mg hard Capsule.

Sodium
This medicine contains less than 1 mmol (23 mg) of sodium per capsule, that is to say it is essentially 'sodium-free.'

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.

3. How to take Atomoxetine

- 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 Atomoxetine 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

How much to take
If you are a child or teenager (6 years or older):
Your doctor will tell you how much Atomoxetine 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 Atomoxetine 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
- Atomoxetine 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.

If you take more Atomoxetine 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. Very rarely, serotonin syndrome has also been reported, a potentially life-threatening condition. (See section 2, Warnings and precautions, Serotonin Syndrome).

Information for children and young people

This information is to help you learn the main things about your medicine called Atomoxetine.
If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.
It may help if you read small bits at a time.

Why have I been given this medicine?
This medicine can help children and young people with 'ADHD'.
- ADHD can make you:
  - run about too much
  - not be able to pay attention
  - act quickly without thinking about what will happen next (impulsive)
- It affects learning, making friends and how you think about yourself. It is not your fault.

While you are taking this medicine
- As well as taking this medicine you will also get help with ways to cope with your ADHD such as talking to ADHD specialists.
- This medicine should help you. But it does not cure ADHD.
- You will need to go to your doctor several times a year for check-ups. This is to make sure the medicine is working and that you are growing and developing all right.
- Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies. If you are having sex, please talk to your doctor about contraception.

Some people cannot have this medicine
You cannot have this medicine if you:
- took a medicine known as a monoamine oxidase inhibitor (MAOI), for example phenelzine, in the last two weeks
- have an eye disease called narrow-angle glaucoma (increased pressure in your eye)
- have a serious problem with your heart
- have serious problems with the blood vessels in your brain
- have a tumour of your adrenal gland

Some people need to talk to their doctor before they start taking this medicine
You need to talk to your doctor if you:
- are pregnant or breastfeeding
- are taking other medicines – your doctor needs to know about all the medicines you are taking
- have thoughts about hurting yourself or others
- have problems with your heart beating too fast or skipping beats while you are not exercising
- hear voices or see things that others do not
- have problems with getting angry easily

How do I take my medicine (capsules)?
- Swallow your medicine with water either with or without food.
- The capsules should not be opened. If the capsule breaks and the contents inside the capsules come into contact with your skin or eyes, get help from an adult.
- Your doctor will tell you how many times a day you should take your medicine.

Black A/s: 280 x 660 mm

If you forget to take Atomoxetine
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 Atomoxetine
If you stop taking Atomoxetine 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 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 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 sides 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**
- 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.	- 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**
- 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	- 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**
- 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	- 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**
- 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	- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease) - prolonged and painful erections

Not known side effects (cannot be estimated from the available data)	
CHILDREN and YOUNG PEOPLE over 6 years	**ADULTS**
- Involuntary teeth grinding (bruxism)	

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
1 Roundwood Avenue,
Stockley Park, Uxbridge,
UB11 1AF
United Kingdom

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

or

Milpharm Limited
1 Roundwood Avenue,
Stockley Park, Uxbridge,
UB11 1AF
United Kingdom

or

Generis Farmacêutica, S.A.
Rua Joao de Deus, n. o 19,
Venda Nova, 2700- 487
Amadora, Portugal

This leaflet was last revised in 10/2025.

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

P1540056

- 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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