PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Atomoxetine 4 mg/ml

oral solution

atomoxetine

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 oral solution 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

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.

Aggressive behaviour, hostility or emotional lability:
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
Atomoxetine may affect or be affected by other medicines. These include:
- Some anti-depressants, 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).

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

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.

Important information about the oral solution
This oral solution can irritate the eye. If the oral solution comes 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 oral solution should also be washed as soon as possible.

Atomoxetine Oral Solution contains
This medicine contains 32.97 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
This medicine contains 2.63 mg of sodium (main component of cooking/table salt) in each ml. This is equivalent to 3.3 % of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 0.8 mg of sodium benzoate in each ml. This medicine contains 9.44 mg of propylene glycol in each ml.
This medicine contains 0.02 mg ethanol (alcohol) in each ml. The amount of alcohol in 25 ml of this medicine (the maximum daily dose) is equivalent to less than 1 ml of beer or 1 ml of wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

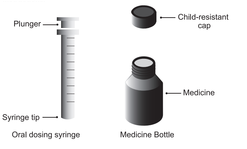
3. HOW TO TAKE ATOMOXETINE

- 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 medicine can be taken either with or without food.
- The oral solution should not be mixed in food or water as this can decrease the

Instructions for Use

Your step-by-step guide for using Atomoxetine.

WHEN USING Atomoxetine, read and carefully follow the step-by-step instructions.



IMPORTANT
DO NOT let your child take the medicine without your help.
DO NOT use the medicine if it has expired. (Check the expiration date on the label.)
DO NOT use the medicine more than 45 days after the first time you open the bottle. See the **Disposal** section to find out what to do with the medicine you don't use.
DO NOT wash the oral dosing syringe with soap or detergent. **DO NOT** put the syringe in the dishwasher. If you do, the syringe may not work as well as it should. Please see steps N through P for cleaning instructions.
It is not recommended to mix Atomoxetine oral solution with food or water since it may affect the taste or prevent a full dose.
Atomoxetine causes irritation of the eye. **Avoid contact with the eye**. If the medicine gets in the eye, flush the eye immediately with water and contact a doctor. Wash hands and surfaces that may have come in contact with the medicine as soon as possible.

STEP 1 GET READY



Gather the items you will need:
- Medicine bottle
- Oral dosing syringe



Wash your hands with soap and water.

Write your child's dose here: _____ ml

Be sure to use the exact dose that your child's doctor prescribed.
If your child's dose is 10 ml OR LESS, you will use the syringe 1 time.
If your child's dose is MORE THAN 10 ml but NOT more than 20 ml, you will use the same syringe 2 times.
If your child's dose is MORE THAN 20 ml, you will use the same syringe 3 times.

STEP 2 PREPARE THE DOSE

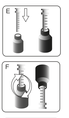


Push down on the cap while twisting it counter clockwise.

Remove the cap from the bottle.



Push the plunger all the way to the syringe tip.



Insert the syringe tip into the opening of the adaptor.

Make sure the syringe tip is fully inside the adaptor.

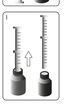


Turn the bottle and the syringe upside down.



Hold the bottle and the syringe with 1 hand. With the other hand, pull the plunger down to draw the proper amount of medicine into the syringe.

Check to make sure the proper dose is in the syringe.



Turn the bottle upright and place it on a flat surface.

Check to see if there is an air gap in the syringe. If there is, empty the medicine back into the bottle and repeat steps D through H. An air gap may result in an incorrect dose.



Remove the syringe from the bottle.

DO NOT touch the plunger.

STEP 3 GIVE THE MEDICINE



Put the syringe tip into a corner of your child's mouth. Tell your child not to bite the syringe.



Push the plunger down until ALL the medicine is in your child's mouth.

DO NOT squirt the medicine into the back of the throat. Make sure your child swallows all the medicine.

If your child's dose is MORE THAN 10 ml, repeat steps D through K to give your child the next part of the dose. Use the same syringe.
See the **dosing chart** below in this document.



Be sure to use the exact dose that your child's doctor prescribed.

CONSILIENT CODE : P1745

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ARTWORK SPECIFICATION		FONTS	COLOURS	DESIGNED BY
Client :	Consilient Health Ltd.	Helvetica Neue (9pt)	Black	Minty
Project :	Dec 2024			VERSION
Item(s) :	Atomoxetine 4 mg/ml oral solution			06 (27/02/2025)
Size :	210 x 800 mm			
Software :	InDesign CC			

amount taken or make the taste less pleasant.
- Taking the medicine at the same time each day may help you remember to take it.

Atomoxetine oral solution is available in a bottle. This is part of a pack which also includes a dosing device containing a 10 ml oral syringe marked in 1 ml increments. Read the instructions which are included in this document on how to use the dosing syringe.

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 much medicine 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).

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 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**
• 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	• 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

Common side effects (may affect up to 1 in 10 people)	
CHILDREN and YOUNG PEOPLE over 6 years	**ADULTS**
• constipation • loss of appetite • upset stomach, indigestion • swollen, reddened and itchy skin • rash • feeling lazy (lethargy) • chest pain • tiredness • weight loss	• 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
• 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 the Yellow Card Scheme at 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 stated on the carton and bottle after 'Exp'. The expiry date refers to the last day of that month.

Do not use the oral solution more than 45 days after the first time you open the bottle. This medicinal product 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Atomoxetine 4 mg/ml contains
- The active substance is atomoxetine hydrochloride. Each ml of oral solution contains atomoxetine hydrochloride equivalent to 4 mg of atomoxetine.
- The other ingredients are sorbitol liquid (E420), xylitol, sucralose, sodium benzoate, sodium dihydrogen phosphate dihydrate, strawberry flavouring, phosphoric acid, sodium hydroxide and purified water.

What Atomoxetine looks like and contents of the pack
Oral solution, 4 mg/ml (clear colourless)
Atomoxetine oral solution is available in a bottle with a child resistant cap containing 100 ml of solution. The pack also includes a dosing device consisting of a 10 ml oral syringe marked in 1 ml increments.
Atomoxetine oral solution is available in a pack containing one bottle and in a multipack of three bottles.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Consilient Health Limited
Floor 3, Block 3, Miesian Plaza,
Dublin 2, D02 Y754
Ireland.

Manufacturer
Laboratórios Basi - Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16
3450-232 Mortágua
Portugal

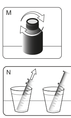
To request a copy of this leaflet in Braille, large print or audio please call 0800 198 5000 (UK only). Please be ready to give the following information:
Product name: Atomoxetine 4 mg/ml oral solution Reference number: PLGB 24837/0193

This leaflet was last revised in March 2025.

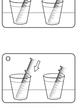
Consilient Health

P1745

STEP 4 CLEAN UP



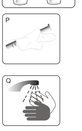
Screw the cap back on the bottle tightly.



Fill a cup with clean water.

DO NOT wash the oral dosing syringe with soap or detergent.

DO NOT remove the plunger from the oral dosing syringe. Put the syringe tip in the water. Pull the plunger up to fill the syringe with water.

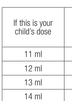


Push the plunger down and squirt the water into the cup or into the sink.



Shake excess water from the syringe.

Dry the syringe with a paper towel.



Wash your hands and your child's hands with soap and water.

DO NOT touch your eyes after handling Atomoxetine. Atomoxetine can irritate your eyes.

See below in this document for commonly asked questions, the dosing chart, and other important information.

DOSING CHART FOR DOSES MORE THAN 10 ml
Use this chart to figure out how to give your child's dose. Find the correct dose in the first column. Talk with your doctor or pharmacist about how to give your child the correct dose.

If this is your child's dose	Put this much Atomoxetine in the syringe the first time	Put this much Atomoxetine in the syringe the second time	Put this much Atomoxetine in the syringe the third time
11 ml	10 ml	1 ml	0
12 ml	10 ml	2 ml	0
13 ml	10 ml	3 ml	0
14 ml	10 ml	4 ml	0
15 ml	10 ml	5 ml	0
16 ml	10 ml	6 ml	0
17 ml	10 ml	7 ml	0
18 ml	10 ml	8 ml	0
19 ml	10 ml	9 ml	0
20 ml	10 ml	10 ml	0
21 ml	10 ml	10 ml	1 ml
22 ml	10 ml	10 ml	2 ml
23 ml	10 ml	10 ml	3 ml
24 ml	10 ml	10 ml	4 ml
25 ml	10 ml	10 ml	5 ml

Commonly asked questions

Q. What if there is an air gap in the oral dosing syringe?
A. **DO NOT** give the medicine to your child. Air gaps may result in an incorrect dose. Empty the medicine back into the bottle and repeat steps D through H.

Q. What if there is too much medicine in the syringe?
A. Keep the syringe tip in the bottle. Hold the bottle upright. Push the plunger down until the correct dose is in the syringe.

Q. What if there is not enough medicine in the syringe?
A. Keep the syringe tip in the bottle. Hold the bottle upside down. Pull the plunger down until the correct dose is in the syringe.

Q. What if I get the medicine in my eye or in my child's eye?
A. Flush the eye immediately with water and call your doctor. As soon as possible, wash hands and surfaces that may have come in contact with the medicine.

Q. How do I travel with this medicine?
A. Make sure you have enough Atomoxetine for the entire trip. Store the medicine in a safe place upright at room temperature.

Q. Can I mix Atomoxetine with food or water before I give it to my child?
A. It is not recommended to mix Atomoxetine oral solution with food or water. This can affect the way Atomoxetine oral solution tastes, or prevent a full dose. You can give your child a glass of water to drink after he or she drinks the entire dose of medicine.

Storage
This medicinal product does not require any special storage conditions.
Keep the bottle and syringe out of the sight and reach of children.

Disposal
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 to protect the environment.

CONSILIENT CODE : P1745

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ARTWORK SPECIFICATION	FONTS	COLOURS	DESIGNED BY
Client : Consilient Health Ltd. Project : Dec 2024 Item(s) : Atomoxetine 4 mg/ml oral solution Size : 210 x 800 mm Software : InDesign CC	Helvetica Neue (9pt)	Black	Minty VERSION 06 (27/02/2025)