

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

## **Atomic Oral Solution**

### **Important information you need to know about the medicine**

Clinical studies carried out on **Atomic Oral Solution** have shown an increase in the frequency of suicidal thoughts and suicide attempts in children and adolescents. Tell the doctor if your child (or if there is a family history):

1. suffers from bipolar disorder
2. has suffered from suicidal thoughts or has attempted suicide before starting treatment with **Atomic Oral Solution**

The risk of suicidal thoughts or suicide attempts is higher at the beginning of treatment and when changing the dose.

During treatment with **Atomic Oral Solution**, you must closely monitor your child's mood and behavior.

If any of the following symptoms appear, contact a doctor immediately: anxiety, irritability, panic attack, sleep disorders, overexcitement, hostility, aggressiveness, impulsiveness, restlessness, mania, depression, suicidal thoughts.

### **The active ingredient and its concentration:**

Each ml of oral solution contains atomoxetine (as hydrochloride) equivalent to 4 mg of atomoxetine.

For a list of inactive and allergenic ingredients, see section 6 "Further information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you or your child has any further questions, contact the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

- **Atomic Oral Solution** contains atomoxetine and is indicated for the treatment of attention deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment program.
- In adults, **Atomic Oral Solution** is indicated for the treatment of attention deficit/hyperactivity disorder (ADHD) when the presence of symptoms of ADHD were pre-existing in childhood.

**Therapeutic group:** centrally acting sympathomimetics.

## How the medicine works

**Atomic Oral Solution** increases the amount of noradrenaline in the brain. Noradrenaline is a chemical that is produced naturally, which 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 starting the medicine for your symptoms to fully improve.

## 2. BEFORE USING THE MEDICINE

### Do not use the medicine if you:

- are hypersensitive (allergic) to the active ingredient (atomoxetine as hydrochloride) or any of the additional ingredients this medicine contains (listed in section 6 “Further information”).
- took medicines known as monoamine oxidase inhibitors (MAOIs), for example phenelzine, in the last two weeks. MAOIs are sometimes used for depression and other mental health problems. Taking **Atomic Oral Solution** with monoamine oxidase inhibitors could cause serious side effects or even be life-threatening. You also need to wait at least 14 days after you stop taking **Atomic Oral Solution** before you take monoamine oxidase inhibitors.
- have an eye disease called narrow-angle glaucoma (increased pressure in your eye).
- have serious problems with your heart that may be affected by an increase in heart rate and/or blood pressure, as these effects may appear due to use of **Atomic Oral Solution**.
- 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 tumor of your adrenal gland (pheochromocytoma).

Do not take **Atomic Oral Solution** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking the medicine. This is because **Atomic Oral Solution** can make these problems worse.

### Special warnings regarding the use of the medicine

Both adult and children should be aware of the following warnings and precautions.

#### Before starting treatment with **Atomic Oral Solution** tell your doctor if you have:

- suicidal thoughts or attempted suicide.
- problems with your heart (including heart defects) or an increased heartbeat. **Atomic Oral Solution** can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. **Atomic Oral Solution** can increase blood pressure.
- low blood pressure. **Atomic Oral Solution** 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 unusual suspiciousness.
- mania (feeling elated or overexcited, which causes unusual behavior) and agitation.
- aggressive feelings.

- unfriendly and feelings angry (hostility).
- a history of epilepsy or have had seizures for any other reason. **Atomic Oral Solution** might lead to an increase in seizure frequency.
- changes in mood or you feel very unhappy.
- repeated and uncontrollable twitching in any parts of the body or you repeat sounds and words.

Before starting treatment with **Atomic Oral Solution**, tell the doctor or pharmacist if any of the above side effects apply to you. This is because **Atomic Oral Solution** can make these side effects worse. Your doctor will want to monitor how the medicine affects you.

### **Tests that your doctor will carry out before you start using the medicine:**

These tests are to decide if **Atomic Oral Solution** is the right medicine for you.

The doctor will measure your:

- blood pressure and heart rate (pulse) before and during treatment with **Atomic Oral Solution**.
- height and weight if you are a child or teenager during treatment with **Atomic Oral Solution**.

The 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 the doctor decide if **Atomic Oral Solution** is the right medicine for you. The doctor may decide that other medical tests are needed before you start taking the medicine.

### **Children and adolescents**

The medicine is indicated for adults, adolescents and children over the age of 6.

### **Drug interactions**

**If you are taking, or have recently taken, any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Your doctor will decide if you can take **Atomic Oral Solution** with your other medicines and in some cases, the doctor may need to adjust your dose or increase your dose more slowly.

Do not take **Atomic Oral Solution** with medicines called MAOIs (monoamine oxidase inhibitors) used for depression. See in section 2 "Do not use the medicine if you".

If you are taking other medicines, **Atomic Oral Solution** may affect how well they work or may cause side effects. If you are taking one or more of the following medicines, check with the doctor or pharmacist before taking **Atomic Oral Solution**:

- medicines that increase blood pressure or regulate blood pressure.
- medicines such as antidepressants, for example imipramine, venlafaxine, mirtazapine, fluoxetine and paroxetine.
- cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with the pharmacist when you get any of these medicines.
- some medicines used to treat mental health conditions.
- medicines that are known to increase the risk of seizures.
- some medicines that cause **Atomic Oral Solution** 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 cause a sharp increase in heart rate, 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 **Atomic Oral Solution**:

- medicines used to regulate heart rhythm.
- medicines that change the concentration of salts in the blood.
- medicines to prevent and treat malaria.
- 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 the doctor or pharmacist before taking **Atomic Oral Solution**.

### **Use of the medicine and food**

The medicine can be taken with or without food. The oral solution should not be mixed in food or water as this can decrease the amount taken or make the taste less pleasant.

### **Pregnancy and breastfeeding**

It is not known if this medicine can affect the fetus or pass into breast milk.

- Do not use this medicine if you are pregnant, unless the doctor has advised you to do so.
- Avoid taking the medicine if you are breastfeeding or discontinue breastfeeding.

If you are:

- pregnant or breastfeeding,
- think that you may be pregnant or are planning a pregnancy,
- planning to breastfeed,

ask your doctor or pharmacist for advice before taking the medicine.

### **Driving and using machines**

You may feel tired, sleepy or dizzy after taking **Atomic Oral Solution**. You should be careful if you are driving a car or operating hazardous machinery until you know how **Atomic Oral Solution** affects you. If you feel tired, sleepy or dizzy, do not drive or operate hazardous machinery. As for children - they should be cautioned against riding bicycles or playing near the road, etc.

### **Important information about the oral solution**

This oral solution can irritate the eye. If the oral solution comes into contact with the eye, flush immediately with water, and refer for medical help. Hands and any other part of the body that may have come into contact with the oral solution should also be washed with water as soon as possible.

### **Important information about some of the ingredients of the medicine**

**Atomic Oral Solution** contains 550 mg maltitol liquid and 35 mg sorbitol in each ml (sorbitol is a source of fructose). If the doctor has told you that you (or your child) have an intolerance to certain 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 the doctor before you (or your child) take or receive the medicine.

The medicine contains 3.4 mg of sodium (the main component of cooking/table salt) in each ml. The maximal dosage of the preparation per day is equivalent to 5.6% of the recommended daily intake of sodium for adults.

The medicine contains 0.8 mg of sodium benzoate in each ml.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

- Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

- The medicine should usually be taken once or twice a day (morning and late afternoon or early evening).
- Children should only take the medicine with help from an adult.
- If you are taking **Atomic Oral Solution** once a day and experience sleepiness or feel sick, the doctor may change your treatment schedule to twice a day.
- Taking the medicine at the same time each day may help you remember to take it.

**The Atomic Oral Solution package** includes three bottles of oral solution, with each bottle containing 100 ml oral solution with a childproof cap and adapter for the bottle. The package also includes a 10 ml measuring syringe with 1 ml hash marks to measure the dose.

**The dosage and treatment regimen will be determined by the doctor only.**

**Do not exceed the recommended dose.**

**If you have accidentally taken a higher dosage**, contact the doctor or the nearest hospital emergency room immediately and bring the medicine package with you. Tell them how much medicine you have taken. The most commonly reported symptoms accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness, tremor and abnormal behavior.

**If you forgot to take this medicine** at the required time, take the dose as soon as you remember, but do 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.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your doctor.

**If you stop taking the medicine**

If you stop taking **Atomic Oral Solution**, there are usually no side effects, but the ADHD symptoms may return. Talk to your doctor before you stop the treatment.

**Tests and follow-up during treatment with the medicine**

The doctor will do some tests:

- before starting treatment – to make sure that **Atomic Oral Solution** is safe and effective for you.
- after starting treatment – will be performed at least every 6 months, but possibly more often.

Tests 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 any problems appeared or if side effects have worsened while taking **Atomic Oral Solution**.

**Duration of treatment**

**Atomic Oral Solution** does not need to be taken all your life. If you take **Atomic Oral Solution** for more than a year, the doctor will check whether further treatment is necessary.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

If you have further questions regarding the use of the medicine, consult with the doctor or pharmacist.

## **4. SIDE EFFECTS**

As with any medicine, the use of **Atomic Oral Solution** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them. The doctor will talk to you about these side effects.

Some side effects can be serious. **If you have one or more of the side effects below, contact the doctor immediately:**

**Uncommon side effects (may affect up to 1 in 100 users):**

- having a fast heartbeat or feeling a very fast heartbeat, abnormal rhythms of the heart
- suicidal thoughts or feelings
- feeling aggressive
- feeling unfriendly and angry (hostility)
- mood swings
- 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 that are not there), believing things that are not true or unusual suspiciousness

**Children and adolescents under the age of 18 have an increased risk of side effects such as:**

- suicidal thoughts or feelings (may affect up to 1 in 100 users)
- mood changes (may affect up to 1 in 10 users)

**Adults have a reduced risk (may affect up to 1 in 1,000 users) of side effects such as:**

- seizures
- psychotic symptoms including hallucinations (hearing voices or seeing things that are not there), believing things that are not true or unusual suspiciousness

**Rare side effects (may affect up to 1 in 1,000 users):**

- liver injury

**Stop taking Atomic Oral Solution and contact the doctor immediately if you have one or more of the following side effects:**

- dark urine
- yellowing of the skin and the eyes
- abdominal pain and tenderness when pressed on the right side under the ribs
- a feeling of sickness (nausea) that is unexplained
- tiredness
- itching
- feeling that you are coming down with the flu

Other side effects reported are included in the following table. If they get serious, tell the doctor or pharmacist:

<b>Very common side effects (may affect more than 1 in 10 users)</b>	
<b>Children and adolescents over the age of 6</b>	<b>Adults</b>
<ul style="list-style-type: none"><li>- headache</li><li>- stomach pain</li><li>- decreased appetite (not feeling hungry)</li><li>- nausea and vomiting</li><li>- sleepiness</li><li>- increased blood pressure</li><li>- increased heart rate (pulse)</li></ul> <p>These side effects may disappear after a while in most patients.</p>	<ul style="list-style-type: none"><li>- nausea</li><li>- dry mouth</li><li>- headache</li><li>- decreased appetite (not feeling hungry)</li><li>- problems falling asleep, staying asleep, waking early</li><li>- increased blood pressure</li><li>- increased heart rate (pulse)</li></ul>

<b>Common side effects (may affect up to 1 in 10 users)</b>	
<b>Children and adolescents over the age of 6</b>	<b>Adults</b>
<ul style="list-style-type: none"> <li>- irritability or agitation</li> <li>- problems sleeping including waking early</li> <li>- depression</li> <li>- feeling sad or hopeless</li> <li>- anxiety</li> <li>- involuntary muscle cramps (tics)</li> <li>- enlarged pupils (the dark center of the eye)</li> <li>- dizziness</li> <li>- constipation</li> <li>- loss of appetite</li> <li>- stomach pain, indigestion</li> <li>- swollen, reddened and itchy skin</li> <li>- rash</li> <li>- lethargy</li> <li>- chest pain</li> <li>- tiredness</li> <li>- weight loss</li> </ul>	<ul style="list-style-type: none"> <li>- agitation</li> <li>- decreased libido</li> <li>- sleep disturbances</li> <li>- depression</li> <li>- feeling sad or hopeless</li> <li>- anxiety</li> <li>- dizziness</li> <li>- an abnormal taste in the mouth or change in taste that does not go away</li> <li>- tremor</li> <li>- tingling or numbness in the hands or feet</li> <li>- sleepiness, drowsy, feeling tired</li> <li>- constipation</li> <li>- stomach pain</li> <li>- indigestion</li> <li>- wind (flatulence)</li> <li>- vomiting</li> <li>- hot flush or flushing</li> <li>- feeling or having a very fast heartbeat</li> <li>- swollen, reddened and itchy skin</li> <li>- increased sweating</li> <li>- rash</li> <li>- difficulty urinating such as not being able to urinate, frequent or hesitant urination, pain during urination</li> <li>- inflammation of the prostate gland (prostatitis)</li> <li>- groin pain in men</li> <li>- failure to obtain an erection</li> <li>- difficulty reaching orgasm</li> <li>- difficulty maintaining an erection</li> <li>- menstrual cramps</li> <li>- lack of strength or energy</li> <li>- tiredness</li> <li>- lethargy</li> <li>- chills</li> <li>- irritability, tension</li> <li>- feeling thirsty</li> <li>- weight loss</li> </ul>

<b>Uncommon side effects (may affect up to 1 in 100 users)</b>	
<b>Children and adolescents over the age of 6</b>	<b>Adults</b>
<ul style="list-style-type: none"> <li>- fainting</li> <li>- tremor</li> <li>- migraine</li> <li>- blurred vision</li> <li>- abnormal skin sensation, such as burning, prickling, itching, or tingling</li> <li>- tingling or numbness in the hands or feet</li> <li>- seizures (fits)</li> <li>- feeling or having a very fast heartbeat (QT prolongation)</li> <li>- shortness of breath</li> <li>- increased sweating</li> <li>- itchy skin</li> <li>- lack of strength or energy</li> </ul>	<ul style="list-style-type: none"> <li>- restlessness</li> <li>- involuntary muscle cramps (tics)</li> <li>- fainting</li> <li>- migraine</li> <li>- blurred vision</li> <li>- heart rhythm abnormal (QT prolongation)</li> <li>- feeling cold in fingers and toes</li> <li>- chest pain</li> <li>- shortness of breath</li> <li>- raised, red, itchy rashes (hives)</li> <li>- muscle spasms</li> <li>- an urge to urinate</li> <li>- abnormal or absence of orgasm</li> <li>- irregular menstruation</li> <li>- ejaculation failure</li> </ul>

<b>Rare side effects (may affect up to 1 in 1,000 users)</b>	
<b>Children and adolescents over the age of 6</b>	<b>Adults</b>
<ul style="list-style-type: none"> <li>- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)</li> <li>- difficulty urinating such as frequent or hesitant urination, pain during urination</li> <li>- prolonged and painful erection</li> <li>- groin pain in males</li> </ul>	<ul style="list-style-type: none"> <li>- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)</li> <li>- prolonged and painful erection</li> </ul>

### **Effects on growth**

Some children experience reduced growth (weight and height) when they start taking **Atomic Oral Solution**, however, with long-term treatment, children recover to the weight and height for their age range. The doctor will watch your child's height and weight over time. If your child is not growing or gaining weight as expected, the doctor may change your child's dose or decide to stop **Atomic Oral Solution** temporarily.

**If a side effect occurs, if one of the side effects worsens or if you or your child suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "[Report Side Effects of Drug Treatment](#)", found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)), that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to "[Unipharm Ltd.](#)".

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton and bottle. The expiry date refers to the last day of that month.
- Store below 25°C and in a place protected from light.  
After the first opening of each bottle, use within two months and no later than the expiry date of the preparation.  
Store in the original package.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Maltitol liquid, Sorbitol, Sodium dihydrogen phosphate, Sucralose, Apricot vanilla flavour, Sodium benzoate, Phosphoric acid, Purified water.

What the medicine looks like and contents of the pack:

**Atomic Oral Solution** is a clear, colorless solution.

**The Atomic Oral Solution package** includes three bottles of oral solution, with each bottle containing 100 ml oral solution with a childproof cap and adapter for the bottle. The package also includes a 10 ml measuring syringe with 1 ml hash marks to measure the dose.

**Registration holder and address:** Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

**Manufacturer and address:** Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 177 39 35463 00.

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