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

The medicine is dispensed with a doctor's prescription only

ATOMIC 18, 25, 40, 60, 80, 100 Film-coated tablets

Composition:

Each film-coated **Atomic 18** tablet contains: Atomoxetine (as HCl) 18 mg

Each film-coated Atomic 25 tablet contains: Atomoxetine (as HCI) 25 mg

Each film-coated Atomic 40 tablet contains:

Atomoxetine (as HCI) 40 mg Each film-coated **Atomic 60** tablet contains:

Atomoxetine (as HCl) 60 mg

Each film-coated Atomic 80 tablet contains: Atomoxetine (as HCI) 80 mg

Each film-coated Atomic 100 tablet contains: Atomoxetine (as HCl) 100 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6: "Further information" and section 2 "Before using the medicine".

Important details you need to know in regards to the

Clinical studies performed with Atomic have shown an increased frequency of suicidal thoughts and suicide attempts in children and adolescents. Tell the doctor if your child (or if there is a family history):

- suffers from bipolar disorder.
- suffers from suicidal thoughts or has tried to commit suicide before starting treatment with Atomic.

The risk of suicidal thoughts or suicide attempt is higher at the beginning of treatment and when adjusting the dosage. Pay close attention to the mood and behavior of your child during treatment with Atomic.

Refer to a doctor immediately if any of the following symptoms occur: Anxiety, nervousness, panic attack, sleeping disorders, overexcitedness, hostility, aggressiveness, lack of impulse control, restlessness, mania, depression, suicidal thoughts.

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

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

Atomic is intended for children over the age of 6, adolescents and adults.

1. WHAT IS THE MEDICINE INTENDED FOR?

Atomic is intended for the treatment of attention deficit hyperactivity disorder (ADHD) in children over the age of adolescents and adults. Atomic should be used as part of a comprehensive treatment program that may include counseling or other therapies.

Therapeutic group: Central nervous system sympathomimetic stimulant (centrally acting sympathomimetics)

In adults, Atomic is used to treat ADHD when the symptoms are bothersome and affect your work and social life and when you suffered from symptoms as a child

How does the medicine Atomic work

Atomic increases the amount of noradrenaline in the brain. Noradrenaline is a chemical agent that is produced naturally. and it 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 taking the medicine until the symptoms fully improve.

2. BÉFORE USING THE MEDICINE

Do not use Atomic if you or your child:

- is sensitive (allergic) to atomoxetine or to any of the additional incredients contained in the medicine (listed in section 6)
- has taken within the past two weeks, a medicine known as a monoamine oxidase inhibitor (MAOI). for example, phenelzine. MAOIs are sometimes used to treat depression and other mental disturbances. Taking Atomic together with MAOIs may cause severe side effects or be life-threatening. In addition, wait at least 14 days from when you stopped taking Atomic until taking
- suffers from an eve disease called narrow-angle glaucoma (increased intraocular pressure).
- suffers from severe cardiac problems that may be affected by an increase in heart rate and/or blood pressure, since these may be side effects of Atomic.
- suffers from severe problems in the blood vessels of the brain such as: a stroke, swelling and weakening of part of a blood vessel (aneurysm) or narrow or blocked blood
- suffer from an adrenal gland tumor (pheochromocytoma). Do not take Atomic if any of the conditions listed above applies to you. If you are uncertain, refer to a doctor or pharmacist before taking Atomic. This is because Atomic may worsen these problems.

Special warnings regarding use of the medicine Children and adults must be aware of the following warnings and precautions

Before using Atomic, tell the doctor if:

- you have thoughts of suicide or have had suicide attempts.
- you have heart problems (including heart defects) or rapid heart beats. Atomic can increase the heart rate (pulse). Sudden death has been reported in patients with heart defects.
- you have high blood pressure. Atomic can increase blood pressure
- you have low blood pressure. Atomic can cause dizziness or fainting in people with low blood pressure.
- you have sudden changes in blood pressure or heart rate. you have cardiovascular disease or medical history of
- stroke you have liver problems. You may need to take a lower dosage
- you have psychotic symptoms including hallucinations (hearing voices or seeing things that do not exist), believing things that are not true or being suspicious.
- you have mania (feeling elated or over-excited, which causes unusual behavior) and agitation.
- you feel aggressive.
- you feel angry and hostile.
- you have a history of epilepsy or have had seizures for any reason. Atomic might lead to an increase in seizure frequency.
- you have mood swings or feel very unhappy.
- you have uncontrollable, repeated twitching of any parts of the body or you repeat sounds and words.

Before starting treatment, tell the doctor or pharmacist if any of the conditions described above apply to you. This is because **Atomic** can make these problems worse. The doctor will want to monitor how the medicine affects you.

Tests that your doctor will perform before you start to take Atomic

These tests are to meant to check if Atomic is the correct medicine for you.

The doctor will measure:

- blood pressure and heart rate (pulse) before and while you are taking Atomic.
- height and weight while taking Atomic, if you are a child or teenager.

The doctor will talk to you about:

- additional medicines you are taking.
- any family history of sudden unexplained death.

- additional medical problems (such as heart problems) that 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 Atomic is the correct medicine for you. The doctor may decide that other medical tests are needed before you start taking the medicine.

Drug interactions

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

Do not take Atomic together with medicines called monoamine oxidase inhibitors (MAOIs) used to treat depression. See section "Do not use Atomic".

If you are taking other medicines. Atomic may affect their activity or may cause side effects. If you are taking any of the following medicines, check with the doctor or pharmacist before taking Atomic:

- medicines that increase blood pressure or regulate blood pressure.
- medicines such as antidepressants, for example: imipramine, venlafaxine, mirtazapine, fluoxetine and
- some cough and cold preparations which contain medicines that can affect blood pressure. It is important to check with the pharmacist if you are taking one or more of these preparations.
- some medicines used to treat mental health conditions.
- medicines that are known to increase the risk of seizures.
- some medicines that cause **Atomic** to stay in the body for longer than normal (such as guinidine 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 following medicines may lead to an increased risk of an abnormal rhythm of the heart when taken with Atomic:

- medicines to control heart rate.
- 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 the doctor or pharmacist before taking Atomic

Use of Atomic and food

Atomic can be taken with or without food.

Pregnancy and breastfeeding It is not known whether this medicine can affect an unborn

- baby or pass into breast milk. - Do not use this medicine during pregnancy, unless the
- doctor has advised you to do so. Avoid taking this medicine if you are breastfeeding, or stop breastfeeding.
- If you:
- are pregnant or breastfeeding
- think you may be pregnant or are planning to become pregnant
- are planning to breastfeed your baby

Consult the doctor or pharmacist before taking this medicine. Driving and using machinery

You may feel tired, sleepy or dizzy after taking Atomic. Exercise caution when driving a car or when operating machinery, until you know how Atomic affects you. Do not drive or operate machinery if you feel tired, sleepy or dizzy. 3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
- Administration to children should only be by an adult.
- If you are taking Atomic once a day and suffer from fatigue or feel sick, the doctor may change the treatment schedule to twice a day.

- The dosage and treatment regimen will be determined by the doctor only. Atomic is available in tablets with different dosages. Your doctor may adjust the dosage until he/she finds the right dosage for you/your child.
- The usual dosage is generally: once or twice a day Taking the medicine at the same time each day will help you/your child remember to take it.
- The medicine can be used with or without food.
- Swallow the medicine with water.
- If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the
- Occasionally, your doctor may stop the treatment with Atomic for a certain period to check the symptoms of the Attention-Deficit Disorder.

Do not exceed the recommended dosage. Tests and follow-up

- The doctor will perform several tests: Before starting treatment - to make sure that **Atomic** is safe and will be of benefit.
- After starting treatment they will be performed at least every 6 months, but possibly more often.

Tests will also be done when the dosage is changed. These tests 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 during the course of treatment with **Atomic** Treatment with **Atomic** may be discontinued if a problem is discovered during the periodic tests.

If you/your child has accidentally taken a higher dosage than necessary, refer immediately to your/your child's doctor, the closest hospital emergency room or a poison control center, and bring the package of the medicine with you. The most common symptoms reported for overdose are gastrointestinal symptoms, sleepiness, dizziness, tremor and unusual behavior.

If you/your child forgot to take this medicine at the required time, take the dose as soon as you remember on that same day. If you missed a dose on one of the days, do not take a double dose on the next day; skip the dose of the forgotten day.

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 the doctor. If you stop taking Atomic

If you stop taking **Atomic**, there are usually no side effects, but the symptoms of ADHD may return. Consult a doctor before stopping treatment.

Long-term treatment

Atomic does not need to be taken throughout life. If you take Atomic for more than one year, the doctor will review your treatment, to see if the medicine is still needed.

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 or your child has further questions regarding the use of the medicine, consult the doctor or pharmacist. 4 SIDE EFFECTS As with any medicine, use of **Atomic** may cause side effects

in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Some side effects may be serious.

Stop using Atomic and refer to a doctor immediately if you are suffering from any of the following effects:

Dark urine; yellow skin or yellow eyes; stomach pain which is sore when you press it (tenderness) on the right side just below your ribs; unexplained nausea; tiredness; itching; feeling that you are coming down with the flu-

Refer to a doctor immediately if one or more of the following side effects occur: Uncommon side effects (may occur in up to 1 in 100

Very fast heartbeat, irregular heart rhythm; suicidal thoughts

or desire to commit suicide; feeling aggressive; feeling hostile and angry: mood swings or mood changes: serious allergic reaction with symptoms of: swelling of the face and throat. breathing difficulties, 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 under the age of 18 are at increased risk of side effects such as: Thinking about or a desire to kill yourself (may occur in up

to 1 in 100 patients); mood swings or mood changes (may occur in up to 1 in 10 patients). Adults are at lower risk (may occur in up to 1 in 1.000

patients) 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.

Rare side effects (may occur in up to 1 in 1,000 patients) Liver injury. Other side effects reported include the following effects.

If the side effects worsen, tell the doctor or pharmacist, Very common side effects (may occur in more than 1 in 10 patients)

Children and young people over the age of 6

Headache; abdominal pain; decreased appetite; nausea or vomiting; sleepiness; hypertension; accelerated heart rate (nulse) Adults

Feeling nauseated: dry mouth: headache: decreased

appetite; difficulty falling asleep, staying asleep and waking up early; hypertension; accelerated heart rate (pulse). These effects may disappear after a while in most patients. Common side effects (may occur in up to 1 in 10 patients) Children and young people over the age of 6

A feeling of irritability and nervousness; sleeping problems and early waking; depression; feeling sad or hopeless; feeling anxious; tics; enlarged pupils (the dark center of the eye); dizziness; constipation; lack of appetite; digestive problems swollen, reddened and itchy skin; rash; feeling lazy, fatigued and sleepy; chest pain; tiredness; weight loss.

Adults

Agitated feeling, decreased libido; sleep disturbances: depression; feeling sad or hopeless; feeling anxious: dizziness; an abnormal sense of taste or change in taste that will not go away; tremor; tingling or numbness in the hands and feet: sleepiness, drowsiness, tired sensation: constipation; abdominal pain; digestive problems; bloating (flatulence); vomiting; hot flushes or flushing; fast heartbeat or palpitations; swollen, reddened and itchy skin; increased sweating; rash; difficulty passing urine, frequent or hesitant urination, pain on urinating; inflammation of the prostate gland (prostatitis); groin pain in men; failure to obtain an erection; delayed ejaculation: difficulty maintaining an erection: menstrual pain; lack of strength or energy; tiredness; feeling lazy, fatigued and sleepy; chills; feeling irritable, tension; feeling thirsty: weight loss.

Uncommon side effects (may occur in more than 1 in 100 patients)

Children and young people over the age of 6

Fainting; tremor; migraine; blurred vision; abnormal skin sensations, such as burning, prickling, itching, or tingling; tingling or numbness in the hands or feet; seizures (fits): feeling or having a very fast heartbeat (QT interval prolongation); shortness of breath; increased sweating; itchy skin: lack of strength or energy.

Adults

Restlessness; tics; fainting; migraine; blurred vision; abnormal heart rhythm (QT interval prolongation); cold sensation in fingers and toes; chest pain; shortness of breath; raised red itchy rash (urticaria); muscle cramps; an urge to urinate; abnormal or absence of orgasm; irregular menstruation; inability to reach ejaculation.

Rare side effects (may occur in up to 1 in 1,000 patients) Children and young people over the age of 6

Poor blood flow causing numbness and pallor in the fingers

and toes (Raynaud's disease); difficulty passing urine, frequent or reduced urination, pain on urination; prolonged and painful erection; groin pain in males.

Adults

Poor blood flow causing numbness and pallor in the fingers and toes (Raynaud's disease); prolonged and painful erection

Effects on growth

Some children experience reduced growth (weight and height) when they start taking Atomic. However, with longterm treatment, children reach the weight and height of their age range. The doctor will watch your child's height and weight during the course of treatment. If your child is not growing or gaining weight as expected, the doctor may change your child's dose or decide to temporarily stop Atomic treatment

If a side effect occurs, if one of the side effects worsens or if you are suffering from a side effect not mentioned in this 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) that directs you to the online form for reporting side effects. 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 safe place out of the reach and sight of children and/or infants in order 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) appearing on the package. The expiry date refers to the last day of that month

Store below 25°C and in a place protected from light. Do not discard medicines in the wastewater or household

waste bin. Consult the pharmacist on how to discard medicines no longer necessary. These measures will help protect the environment.

6. FURTHER INFORMATION In addition to the active ingredient, the medicine also

Microcrystalline cellulose, Calcium hydrogen phosphate anhydrous, Croscarmellose sodium, Magnesium stearate. Opadry OY 6503 blue, Opadry 02B220022 yellow.

What the medicine looks like and the contents of the package: The medicine is packaged in trays (blisters), which are

inserted into a carton box. **Atomic** is available in pack sizes of 4, 7, 14, 15, 20, 28 and 30 tablets. Not all pack size are marketed Atomic 18 tablets are film-coated, rounded, biconvex and

green, with a score line on one side. Atomic 25, 40 tablets are film-coated, round, biconvex and green, with a score line on one side.

Atomic 60 tablets are film-coated, oblong, biconvex and green, with a score line on one side. Atomic 80 tablets are film-coated, oblong, biconvex and

green, with a score line on one side. Atomic 100 tablets are film-coated, oval, biconvex and green, with a score line on one side.

Registration holder and address: Unipharm Ltd., P.O.Box 21429. Tel Aviv. 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park. Registration number of the medicine in the National Drug

167 82 36233 00

Atomic 25: 160 12 35129 01 Atomic 40: 160 13 35130 01 160 14 35131 01 Atomic 60: Atomic 80: 167 83 36234 00 Atomic 100: 167 84 36235 00

Registry of the Ministry of Health:

Atomic 18:

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