

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

The medicine is dispensed with a doctor's prescription only

LISSIN 20 MG

LISSIN 30 MG

LISSIN 40 MG

LISSIN 50 MG

LISSIN 60 MG

LISSIN 70 MG

Tablets

The active ingredient and its quantity:

Each **Lissin 20 mg** tablet contains lisdexamfetamine dimesylate 20 mg

Each **Lissin 30 mg** tablet contains lisdexamfetamine dimesylate 30 mg

Each **Lissin 40 mg** tablet contains lisdexamfetamine dimesylate 40 mg

Each **Lissin 50 mg** tablet contains lisdexamfetamine dimesylate 50 mg

Each **Lissin 60 mg** tablet contains lisdexamfetamine dimesylate 60 mg

Each **Lissin 70 mg** tablet contains lisdexamfetamine dimesylate 70 mg

Warning: dependence, abuse, and addiction

Lissin has a high potential for dependence, addiction and abuse which can lead to development of substance use disorder, including addiction. Dependence and abuse of central nervous system stimulants, including Lissin, can lead to overdose and death.

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

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

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

The medicine is not intended for children under 6 years of age with ADHD or patients under 18 years of age with binge eating disorder (BED).

1. WHAT IS THE MEDICINE INTENDED FOR?

Lissin is intended for the treatment of attention deficit hyperactivity disorder (ADHD).

Lissin can improve attention and concentration and decrease impulsiveness and hyperactivity in patients with ADHD.

Lissin is intended for the treatment of moderate to severe binge eating disorder. It may reduce the number of binge eating days in BED patients.

Lissin is not intended for weight loss. It is not known if **Lissin** is safe and effective for the treatment of obesity.

Lissin is intended only for patients over the age of 6 years with ADHD and for patients over the age of 18 years with BED.

Therapeutic group – Central nervous system stimulant.

There is no information about the safety and effectiveness of **Lissin** for the treatment of ADHD in children under 6 years of age or of BED in patients under 18 years of age.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You or your child is sensitive (allergic) to the active ingredient (Lisdexamfetamine dimesylate) or to any of the additional ingredients contained in the medicine (see section 6 “Further information”).
- You or your child is taking or has taken within the past 14 days an anti-depressant from the monoamine oxidase inhibitors (MAOIs) group.
- You or your child is sensitive to, allergic to, or had an allergic reaction to other medicines that stimulate the central nervous system.
- You were treated with the antibiotic linezolid or intravenous methylene blue.

Special warnings regarding use of the medicine

- **Lissin** is a medicine defined as a controlled substance because it can lead to dependence or be abused. Keep the medicine in a safe place to prevent abuse.
- Keep **Lissin** in a safe place to protect it from theft.

Selling or giving **Lissin** to others may cause harm and is against the law.

Tell the attending doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or illegal drugs.

Lissin is a stimulant which may cause the following problems in some of the users:

a. Heart-related problems:

- sudden death in patient suffering from heart problems, heart defect
- sudden death, stroke and heart attack in adults
- increased blood pressure and heart rate

Tell the doctor if you or your child has heart problems, a heart defect, high blood pressure, or a family history of any of these problems.

Before starting to use **Lissin**, the doctor should check you or your child for heart problems.

During treatment with **Lissin**, the doctor should check your or your child’s blood pressure and heart rate regularly. During treatment with **Lissin**, inform the

doctor immediately if you or your child shows signs of heart problems such as chest pain, shortness of breath, or fainting.

b. Mental (psychiatric) problems including:

- New or worsened behavioral disturbances and thought disturbances
- New or worsening of bipolar illness

New psychotic symptoms:

- Hearing voices
- Believing things that are not true
- Being suspicious
- New manic symptoms

Tell the doctor about any mental problems you or your child has, or about a family history of suicide, bipolar illness or depression.

Call the attending doctor immediately, if during treatment with **Lissin** you or your child has new or worsening mental symptoms or problems such as:

- Seeing or hearing things that are not real
- Believing things that are not real
- Being suspicious

c. Circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's syndrome):

- The fingers and toes may feel cool, painful, numb
- The fingers and toes may change color from pale to blue and red

Tell the attending doctor if you or your child has **numbness, pain, skin color change or sensitivity to temperature in the fingers and toes.**

Refer to a doctor immediately if you have or your child has signs of unexplained wounds that appear on the fingers or toes while taking **Lissin**.

Before treatment with Lissin, tell the doctor or pharmacist if:

- You or your child has or if there is a family history of:
 - Heart problems, heart defects, heart disease, high blood pressure
 - Mental problems such as psychosis, mania, bipolar illness, or depression
 - Circulation problems in the fingers and toes
 - Kidney problems. The doctor may lower the dosage
 - **Repeated movements or sounds (tics) or Tourette's syndrome**

Tests and follow-up

During the course of treatment, you may also be referred for routine blood, heart and blood pressure tests.

Height and weight of children should be checked frequently during the course of treatment with **Lissin**. Treatment with **Lissin** may be discontinued if your child is not growing or gaining weight. The doctor may stop the treatment with **Lissin** in order to check ADHD or BED symptoms.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Selective serotonin reuptake inhibitors (SSRIs)
- Serotonin norepinephrine reuptake inhibitors (SNRIs)
- Medicines called triptans used to treat migraine headaches
- Lithium

- Fentanyl
- Tramadol
- Tryptophan
- Buspirone
- St. John's wort (*Hypericum perforatum*)
- Anti-depressants including monoamine oxidase inhibitors (MAOIs), such as: selegiline, isocarboxazid, phenelzine, tranylcypromine (also see in section 2 "Do not use the medicine if")
- Vitamin C (ascorbic acid)
- Baking soda (bicarbonate)
- Substances that make the urine more alkaline such as acetazolamide, thiazides
- Substances that make the urine more acidic such as ammonium chloride, sodium acid phosphate, methenamine salts
- Tricyclic antidepressants such as desipramine, protriptyline

Lissin can affect the way other medicines work and other medicines can affect it, which can cause serious side effects.

Know which medicines you take. Keep a list of them to show the doctor and pharmacist when you get a new medicine.

Use of the medicine and food

The tablet can be taken with or without food.

Use of the medicine and alcohol consumption

It is not recommended to drink alcoholic beverages during the course of treatment with **Lissin**. Alcohol may worsen side effects which occur during treatment with **Lissin**.

Pregnancy and breastfeeding

Breastfeeding during treatment with **Lissin** is not recommended. If you are pregnant or might be pregnant, consult the doctor before starting to use the medicine.

If you are breastfeeding or plan to breastfeed, the medicine passes into breast milk. Consult the doctor before starting to use the medicine.

Driving and using machinery

Do not drive or operate dangerous machinery while using the medicine until you know how **Lissin** affects you.

Important information regarding some of the ingredients of the medicine

Lissin contains less than 1 mmol (23 mg) sodium per dose and is considered to be essentially "sodium-free".

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

The usual dosage is generally one **Lissin** tablet every morning.

Lissin 20, 30, 40, 50, 60: If needed, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

Lissin 70: Do not halve the tablet. There is no information regarding crushing or chewing the tablet.

Do not exceed the recommended dose.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the scheduled time, take the next dose at the usual time and consult the doctor. **Do not take a double dose.** Adhere to the treatment regimen recommended by the doctor.

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

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

4. SIDE EFFECTS

As with any medicine, the use of **Lissin** 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.

Consult a doctor immediately if you have any of the following side effects:

- Slowed growth (height and weight) in children
- Circulation disturbances in the blood vessels of the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon). Symptoms may include:

- Numb, cold, painful feeling in the fingers or toes
- Change in color from pale to blue or red of the fingers or toes

Tell your doctor if you or your child has numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

Call your doctor immediately if you or your child has signs of unexplained wounds appearing on the fingers or toes during the course of treatment with **Lissin**.

- New or worsening tics or worsening Tourette's syndrome. Tell your doctor if you or your child has new or worsening tics or worsening Tourette's syndrome during treatment with **Lissin**.
- **Serotonin syndrome** – A potentially life-threatening syndrome that can occur when **Lissin** is taken with certain other medicines. Stop taking **Lissin** and call the doctor or proceed to the nearest hospital emergency room immediately if you or your child develops one of the following symptoms of serotonin syndrome:
 - Agitation
 - Fast heartbeat
 - Flushing
 - Seizures
 - Coma
 - Sweating
 - Loss of coordination

- Confusion
- Dizziness
- Tremors, stiff muscles or muscle twitching
- Hallucinations (seeing or hearing things that are not real)
- Changes in blood pressure
- High body temperature (hyperthermia)
- Nausea, vomiting, diarrhea

Very common side effects in children 6 to 17 years old and adults with ADHD (effects that occur in more than one user in ten):

- Loss of appetite (anorexia)
- Decreased appetite
- Diarrhea
- Anxiety
- Weight loss
- Dizziness
- Nausea
- Vomiting
- Sleep disturbances
- Dry mouth
- Agitation
- Upper stomach pain
- Headache

Common side effects of Lissin in patients with ADHD (effects that occur in 1-10 in 100 users):

- Anxiety
- Nausea
- Weight loss
- Diarrhea
- Dizziness
- Vomiting
- Tremor
- Rash
- Mood swings
- Fever
- Sleepiness or tiredness
- Feeling agitated, restlessness
- Increased blood pressure
- Excessive sweating
- Inability to achieve or maintain an erection
- Decreased sex drive
- Being unusually active
- Rapid heart rate
- Difficulty breathing
- Tics
- Anorexia
- Dry mouth
- Palpitations
- Abnormal ECG results showing ventricular hypertrophy
- Psychomotor hyperactivity

Uncommon side effects of Lissin in patients with ADHD (effects that occur in 1-10 in 1,000 users):

- Excessive talkativeness
- Chest pain
- Anger
- Obsessive skin scratching
- Headache
- Depression
- Paranoia

Very common side effects of Lissin in patients with BED (effects that occur in more than one user in ten):

- Dry mouth
- Insomnia

Common side effects of Lissin in patients with BED (effects that occur in 1-10 in 100 users):

- Decreased appetite
- Increased heart rate
- Agitation
- Constipation
- Anxiety
- Diarrhea
- Weight loss
- Increased sweating
- Vomiting
- Inflammation of the stomach and bowel
- Paresthesia (feeling prickles on the skin for no apparent reason)
- Itch
- Upper abdominal pain
- Increased energy
- Urinary tract infection
- Nightmares
- Restlessness
- Pain in the lower part of the throat

Uncommon side effects of Lissin in patients with BED (effects that occur in 1-10 in 1,000 users):

- Increased heart rate
- Headache
- Upper abdominal pain
- Difficulty breathing
- Rash
- Insomnia
- Hypersensitivity
- Agitation
- Anxiety

Additional side effects of unknown frequency:

- Palpitations, cardiomyopathy
- Mydriasis – widening of the pupils of the eyes
- Diplopia – double vision

- Blurred vision or difficulty focusing on objects
- Eosinophilic hepatitis – allergic liver injury with possible yellowing of the eyes and/or skin
- Severe allergic reaction characterized by a sharp drop in blood pressure, difficulty breathing, urticaria/itching
- Hypersensitivity
- Uncontrolled involuntary movements
- Bad taste in the mouth
- Tics
- Grinding of the teeth
- Depression
- Compulsive scratching of the skin
- Hair loss
- Aggressiveness
- Stevens-Johnson syndrome
- Chest pains
- Angioedema
- Urticaria
- Seizures
- Changes in sex drive
- Frequent or prolonged erection
- Constipation
- Disintegration of muscle tissue (rhabdomyolysis)
- Intestinal ischemia

If a side effect occurs, if one of the side effects worsens, or if you 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), 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 safe 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 package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C and in a place protected from light.
- Do not discard any medicines via the wastewater or household waste. Ask the pharmacist how to dispose of medicines that you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
microcrystalline cellulose, croscarmellose sodium, copovidone, acesulfame potassium, magnesium stearate.

What the medicine looks like and the contents of the package:

Lissin is packaged in trays (blisters) which are inserted into a carton box. Each package contains 20, 28 or 30 tablets. Not all package sizes may be marketed.

Lissin 20, 30, 50 are round, biconvex, white to off-white tablets with a break line.

Lissin 40 is a hexagonal, biconvex, white to off-white tablet with a break line.

Lissin 60 is a capsule-shaped, biconvex, white to off-white tablet with a break line.

Lissin 70 is an oval, biconvex, white to off-white tablet.

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

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

Drug registration numbers in the National Drug Registry of the Ministry of Health:

Lissin 20: 176-71-37820-99

Lissin 30: 176-87-37763-99

Lissin 40: 176-88-37821-99

Lissin 50: 176-72-37764-99

Lissin 60: 176-73-37822-99

Lissin 70: 176-74-37765-99

Revised in July 2024.



05A24

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