

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PRO-LISDEXAMFETAMINE

Lisdexamfetamine Dimesylate Capsules

Read this carefully before you start taking **PRO-LISDEXAMFETAMINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-LISDEXAMFETAMINE**.

Serious Warnings and Precautions

Drug dependence: Like other stimulants, PRO-LISDEXAMFETAMINE has the potential to be abused. This can lead to you becoming dependent on PRO-LISDEXAMFETAMINE or feeling like you need to take more of it over time.

What is PRO-LISDEXAMFETAMINE used for?

PRO-LISDEXAMFETAMINE is used to treat:

- Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age or older, adolescents and adults. Treatment with PRO-LISDEXAMFETAMINE for ADHD should be combined with other measures, such as psychological counselling, educational and social measures, as part of a total treatment program. **PRO-LISDEXAMFETAMINE is NOT recommended for use in children with ADHD under 6 years of age.**
- moderate to severe Binge Eating Disorder (BED) in adults. **PRO-LISDEXAMFETAMINE is NOT recommended for use in children with BED under 18 years of age.**

Use of other stimulant drugs for weight loss has been associated with serious heart-related problems. It is not known if PRO-LISDEXAMFETAMINE is safe and effective for weight loss.

How does PRO-LISDEXAMFETAMINE work?

PRO-LISDEXAMFETAMINE belongs to a group of medicines called central nervous system stimulants. PRO-LISDEXAMFETAMINE is a prodrug, which means that the medicinal ingredient PRO-LISDEXAMFETAMINE is inactive until the body breaks it down into its active form called dextroamphetamine. It works by raising the levels of chemicals in the brain called dopamine and norepinephrine.

- This helps to increase attention and decrease impulsiveness and hyperactivity in patients with ADHD;
- This may help to reduce the number of binge eating days in adults with BED.

What are the ingredients in PRO-LISDEXAMFETAMINE?

Medicinal ingredients: lisdexamfetamine dimesylate.

Non-medicinal ingredients: Croscarmellose sodium, magnesium stearate and microcrystalline cellulose. The capsule shells contain edible ink (black iron oxide, potassium hydroxide, propylene glycol, shellac), gelatin, titanium dioxide, and one or more of the following: FD&C Blue #1, FD&C Blue #2, Black Iron Oxide, Red Iron Oxide, Yellow Iron Oxide.

PRO-LISDEXAMFETAMINE comes in the following dosage forms:

- **Capsules:** 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg

Do not use PRO-LISDEXAMFETAMINE if you/your child:

- are allergic to amphetamines, the medicinal ingredient PRO-LISDEXAMFETAMINE or its active form (i.e., dextroamphetamine), or any of the other ingredients in PRO-LISDEXAMFETAMINE.
- are sensitive to, allergic to or had a reaction to other stimulant medicines.
- have advanced arteriosclerosis (hardened arteries).
- have symptoms of heart disease.
- have moderate to severe high blood pressure.
- are agitated.
- have glaucoma (an eye disease with increased pressure in the eye).
- have hyperthyroidism (an overactive thyroid gland).
- are taking or have recently taken (in the past 14 days) any medications from the group called monoamine oxidase inhibitors (MAOIs).
- have a history of drug abuse.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-LISDEXAMFETAMINE. Talk about any health conditions or problems you may have, including if you/your child:

- have structural heart abnormalities, cardiomyopathy, serious heart rhythm abnormalities or other serious heart problems.
- have a family history of sudden cardiac death or death related to heart problems.
- have mild high blood pressure.
- do strenuous exercise.
- have a history of seizures (convulsions, epilepsy) or have had abnormal brainwave tests (electroencephalogram; EEGs).
- have or have a family history of tics (movements or sounds that you cannot control) or Tourette's syndrome.
- take other medications for ADHD.
- take blood pressure medications or other medicines that can affect blood pressure.
- have or have a family history of mental health problems, including:
 - psychosis,
 - mania,
 - bipolar disorder,
 - depression, or
 - suicide.
- have severe kidney problems, including if you are undergoing dialysis.
- have a history of drug abuse or alcoholism.

- are pregnant, think you are pregnant or are planning to become pregnant.
- are breastfeeding or plan to breastfeed.

Other warnings you should know about:

Dependence and tolerance:

- Amphetamines, such as PRO-LISDEXAMFETAMINE, have the potential to cause drug abuse and misuse.
- Abuse of amphetamines can lead to dependence, tolerance, social disorders and possibly serious heart problems and death.
- Long term misuse of amphetamines may cause:
 - skin diseases
 - sleeping problems
 - personality changes
 - anxious and distressful feelings
 - rash, uncontrolled behavior
 - psychosis
 - schizophrenia
- Doctor supervision is needed when you or your child stop taking PRO-LISDEXAMFETAMINE. Suddenly ending treatment when taking higher doses of PRO-LISDEXAMFETAMINE for a long period of time can cause:
 - extreme fatigue
 - depression
 - changes in sleep patterns
- PRO-LISDEXAMFETAMINE should only be given under close medical supervision to patients whose condition has been properly diagnosed.

Driving and using machines: PRO-LISDEXAMFETAMINE can affect your ability to drive and use tools or machinery. You should not drive or use tools or machinery until you know how you respond to PRO-LISDEXAMFETAMINE.

Pregnancy and breastfeeding:

- Taking PRO-LISDEXAMFETAMINE during pregnancy can harm your unborn baby. It should not be used during pregnancy unless your healthcare professional has determined the potential benefits outweigh the potential risks to your baby. Your healthcare professional will discuss these risks with you. If you discover that you are pregnant while taking PRO-LISDEXAMFETAMINE, tell your healthcare professional right away.
- PRO-LISDEXAMFETAMINE can pass through your breast milk and may harm your baby. You should consult with your healthcare professional to determine if you should stop breastfeeding or discontinue PRO-LISDEXAMFETAMINE.

The following have been reported with use of PRO-LISDEXAMFETAMINE and other medicines

used to treat ADHD.

Growth in children: Slower growth (in weight and/or height) has been reported with the use of PRO-LISDEXAMFETAMINE in children. This risk increases as the dose of PRO-LISDEXAMFETAMINE increases. Your healthcare professional will carefully watch your child's height and weight. If your child is not growing or gaining weight as expected, your healthcare professional may stop treatment.

Heart-related problems: The following heart-related problems have been reported in people taking medications to treat ADHD, like PRO-LISDEXAMFETAMINE:

- Sudden death in patients who have heart problems or heart defects
- Stroke and heart attack in adults
- Increased blood pressure and heart rate

Sudden death has been reported in association with stimulant drugs for ADHD treatment in children and adolescents with structural heart abnormalities. PRO-LISDEXAMFETAMINE generally should not be used in children, adolescents or adults with known structural heart abnormalities. There may be additional heart-related risks if you are overweight or obese.

Tell your healthcare professional if you/your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your healthcare professional will check:

- you/your child for heart problems before starting PRO-LISDEXAMFETAMINE.
- your/your child's blood pressure and heart rate before and regularly during treatment with PRO-LISDEXAMFETAMINE.

Seek immediate medical help if you/your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking PRO-LISDEXAMFETAMINE.

Mental health problems: The following mental health problems have been reported in people taking stimulant medicines like PRO-LISDEXAMFETAMINE:

- New or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicidal actions (suicide attempt, suicidal ideation and completed suicide).
- New or worse symptoms of bipolar disorder (extreme mood swings, with periods of impulsiveness or unusual excitement, switching between periods of sadness).
- New or worse aggressive behavior or hostility.
- New psychotic symptoms (such as hearing voices, believing things that are not true, being suspicious) or new mania (unusually excited, over-active or un-inhibited).

These new or worse mental symptoms may be more likely to occur if you/your child have mental disorders that you may or may not know about. Tell your doctor about any mental problems or about any personal or family history of suicide, bipolar illness, or depression you or your child have.

A small number of patients taking ADHD medicines may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of

suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time during treatment, particularly at the start or during dose changes, and also after stopping PRO-LISDEXAMFETAMINE. **Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately. Close observation by a doctor is necessary in this situation.**

Serotonin toxicity (also known as Serotonin Syndrome): Serotonin toxicity is a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take PRO-LISDEXAMFETAMINE with certain anti-depressants or migraine medications. Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Raynaud's Phenomenon (episodes of reduced blood flow): Stimulant medicines, such as PRO-LISDEXAMFETAMINE, are associated with Raynaud's Phenomenon. During treatment with PRO-LISDEXAMFETAMINE, your healthcare professional may check for problems with the circulation in your fingers and toes, including numbness, feeling cold or pain.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take PRO-LISDEXAMFETAMINE if you:

- are taking or have recently taken (in the last 14 days) any MAOIs such as phenelzine, tranylcypromine, or moclobemide as you may have serious side effects.

The following may interact with PRO-LISDEXAMFETAMINE:

- other medications used to treat ADHD such as guanfacine.
- medicines used to treat depression or anxiety such as:
 - certain tricyclic antidepressants,
 - selective serotonin reuptake inhibitors (SSRIs), and
 - serotonin and noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine.
- certain medicines used to treat migraines such as sumatriptan, rizatriptan or zolmitriptan.
- medicines used to manage psychotic symptoms such as pimozide, haloperidol and chlorpromazine.
- medicines that make the urine more acidic such as ammonium chloride and sodium acid phosphate, as well as the dietary supplement ascorbic acid (vitamin C).
- medicines that make urine more alkaline such as sodium bicarbonate, acetazolamide, and thiazides.

- blood pressure medications or other medicines that can affect blood pressure such as beta blockers and norepinephrine.
- opioid medicines, used to relieve pain.
- lithium, used to treat manic episodes in bipolar disorder.
- modafinil, used to treat sleepiness due to narcolepsy.
- St John's Wort, a herbal remedy.

How to take PRO-LISDEXAMFETAMINE:

- Take PRO-LISDEXAMFETAMINE once each day in the morning, with or without food.
- Avoid taking PRO-LISDEXAMFETAMINE in the afternoon as it may cause insomnia.
- If you/your child were prescribed PRO-LISDEXAMFETAMINE:
 - swallow the capsule whole with water; or
 - for patients with problems swallowing medicines, the capsule can be opened and all of the medication powder can be sprinkled over yogurt, water, or orange juice. Mix the medication powder thoroughly until the powder is completely dispersed. Make sure to break up any lumps of powder with a spoon. Eat the entire yogurt or drink all of the water or orange juice immediately. Do not store it for future use. Do not be alarmed if you see a film on the inside of the glass or container; this film contains non-medicinal ingredients. Do not divide the dose.
- As with all medicines, never share PRO-LISDEXAMFETAMINE with anyone else.

Usual dose:

- **To treat Attention Deficit Hyperactivity Disorder (ADHD)** (children 6 years of age or older, adolescents and adults):

Your healthcare professional will decide the dose that is right for you/your child. Always follow the directions of your healthcare professional and never change the dose or stop taking PRO-LISDEXAMFETAMINE without discussing it with your healthcare professional first.

The usual dose is 20 mg to 60 mg once a day. Take PRO-LISDEXAMFETAMINE in the morning exactly as prescribed. Your healthcare professional may adjust the dose until it is right for you/your child. The maximum daily dose is 60 mg.

From time to time, your healthcare professional may interrupt your/your child's treatment to check your/your child's symptoms while you/your child are not taking the medicine.

- **To treat moderate to severe Binge Eating Disorder (BED)** (adults):

The recommended starting dose is 30 mg once a day in the morning. Your healthcare professional will then gradually increase your daily dose by 20 mg each week. They will do this until you're taking 50 mg to 70 mg once a day in the morning. The maximum daily

dose is 70 mg.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-LISDEXAMFETAMINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child forget to take your/his or her dose in the morning, wait until the next day and take or have him or her take the usual dose at the usual time in the morning. Do not take an afternoon dose. Do not double the dose to make up for the missed dose.

What are possible side effects from using PRO-LISDEXAMFETAMINE?

These are not all the possible side effects you may have when taking PRO-LISDEXAMFETAMINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- headache, dizziness, feeling like your environment is moving or spinning (vertigo)
- dry mouth, decreased appetite, anorexia (eating disorder)
- trouble sleeping or falling asleep, feeling sleepy
- upper abdominal pain, constipation or diarrhea, vomiting or nausea, indigestion
- numbness, or pricking or tingling sensations in the hands, arms, legs or feet
- fever, upper respiratory tract infection, stuffy nose or sore throat
- feeling irritable, anxious or jittery, lack or abundance of energy, rapid and sometimes exaggerated changes in mood
- decreased sex drive, inability to get or keep an erection
- bladder infection
- skin rash, hives, itchy skin
- ringing in the ears
- unusual dilation or widening of the pupils
- weight changes
- changes in taste
- excessive sweating
- nightmares
- clenching of teeth
- hair loss
- memory problems
- muscle aches and pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Anxiety	√		
New or worsening tics: movements or sounds that you cannot control		√	
Slowing of growth (height and weight) in children		√	
Palpitation (fast-beating, fluttering or pounding heart)		√	
UNCOMMON			
Aggressive behaviour or hostility		√	
Allergic reaction: difficulty swallowing or breathing, and throwing up, swelling of the face, lips, tongue or throat, hives or rash			√
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse		√	
New or worsening mental health problems: paranoia, delusions, hallucinations (seeing, feeling or hearing things that are not there), mania (feeling unusually excited, over-active, or uninhibited), compulsions		√	
Vision problems: changes in vision or blurry vision		√	
UNKNOWN FREQUENCY			
Epistaxis and Contusion: unexplained nosebleeds or bruising	√		
Heart attack: severe, crushing chest pain that can radiate into the arm and/or jaw, upper back or neck, palpitation, shortness of breath, nausea, vomiting, sweating,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
indigestion, heartburn, dizziness, extreme fatigue, upper body discomfort			
Seizures (fits): uncontrollable shaking with or without loss of consciousness			√
Intestinal ischemia (blood flow to your intestines decreases due to a narrowed or blocked blood vessel): sudden or worsening abdominal pain (usually severe), urgent need to have a bowel movement, frequent, forceful bowel movements, nausea, vomiting, diarrhea, blood in your stool, confusion in older adults			√
Liver Disorder yellowing of the skin or whites of the eyes (jaundice), dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite			√
Raynaud's phenomenon (episodes of reduced blood flow): cold feeling in fingers and toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue		√	
Stevens-Johnson syndrome (SJS) (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			√
Suicidal behaviour: thoughts or actions about hurting or killing yourself			√
Serotonin toxicity (also known as Serotonin Syndrome): feeling of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (above 38°C), rigid muscles			√
Cerebrovascular disorders (problems with the blood vessels in the brain, stroke): severe headaches, weakness or paralysis of			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
any body part, or problems with coordination, vision, speaking, finding words or with your memory			
Rhabdomyolysis (breakdown of damaged muscle): muscle weakness, muscle pain, muscle spasms, red-brown coloured urine		√	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or fast or uneven heartbeat.	√		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at 15°C to 30°C. Protect from heat and humidity.
- Keep out of reach and sight of children.

If you want more information about PRO-LISDEXAMFETAMINE:

- Talk to your healthcare professional.

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html>); or by contacting Pro Doc Ltée : 1-800-361-8559, www.prodoc.qc.ca, medinfo@prodoc.qc.ca

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