

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### PrATIVAN

#### lorazepam oral tablets, lorazepam sublingual tablets

Read this carefully before you start taking **ATIVAN** 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 **ATIVAN**.

#### Serious Warnings and Precautions

##### Addiction, Abuse and Misuse:

Even if you take ATIVAN exactly as you are told, you are at risk for abuse, misuse and addiction, physical dependence and withdrawal. Abuse and misuse can result in overdose or death, especially if you take ATIVAN with:

- opioids
- alcohol or
- illicit drugs

Your healthcare professional should:

- talk to you about the risks of treatment with ATIVAN as well as other treatment (including non-drug) options
- assess your risk for these behaviours before prescribing ATIVAN
- monitor you while you are taking ATIVAN for the signs and symptoms of misuse and abuse. IF you feel like you are craving ATIVAN, or not using it as directed, talk to your healthcare professional right away

Store ATIVAN in a secure place to avoid theft or misuse.

##### Withdrawal:

If you suddenly stop taking ATIVAN, lower your dose too fast, or switch to another medication, you can experience severe or life-threatening withdrawal symptoms (see Other warnings you should know about).

- Always contact your healthcare professional before stopping or lowering your dose of ATIVAN or changing your medicine

##### ATIVAN with Opioids:

Taking ATIVAN with opioid medicines can cause:

- severe drowsiness
- decreased awareness
- breathing problems
- coma
- death

### **What is ATIVAN used for?**

ATIVAN is used in adults for:

- the short-term relief of severe anxiety symptoms in people with anxiety problems.
- the relief of anxiety before surgery.

ATIVAN is not recommended for mild to moderate anxiety and tension associated with the stresses of everyday life.

If you are 65 years or older, talk to your healthcare professional before starting ATIVAN. ATIVAN may not be an effective treatment for you and you may be more sensitive to experiencing side effects.

### **How does ATIVAN work?**

ATIVAN is a benzodiazepine with sedative (calming) properties which help in the treatment of anxiety.

### **What are the ingredients in ATIVAN?**

Medicinal ingredients: Lorazepam

Non-medicinal ingredients:

ATIVAN oral tablets: lactose, magnesium stearate, microcrystalline cellulose, polacrillin potassium

ATIVAN sublingual tablets: D&C yellow No. 10 aluminum lake (0.5 mg), FD&C blue No. 1 aluminum lake (0.5 mg), FD&C blue No. 2 aluminum lake, (2 mg ) FD&C yellow No. 6 aluminum lake (0.5 mg), lactose, magnesium stearate, microcrystalline cellulose, corn starch

### **ATIVAN comes in the following dosage forms:**

Oral tablets: 0.5 mg, 1 mg, 2 mg

Sublingual tablets: 0.5 mg, 1 mg, 2 mg

### **Do not use ATIVAN if you:**

- are allergic to the group of medicines known as benzodiazepines (such as diazepam, clonazepam, chlordiazepoxide, bromazepam or flurazepam)
- are allergic to lorazepam or any of the other ingredients in ATIVAN (see What are the ingredients in ATIVAN)
- have myasthenia gravis (a chronic disease with muscle weakness)
- have acute narrow angle glaucoma (a disease of the eye which causes progressive vision loss)

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

- have ever had a problem with:
  - substance use, including prescribed or illegal drugs, or
  - alcohol
- have ever had seizures or convulsions (violent uncontrollable shaking of the body with or without loss of consciousness)
- have a lung disease or breathing problems (such as chronic obstructive pulmonary disease (COPD), sleep apnea syndrome)
- have a history of depression, suicide attempts or a mental health problem called psychosis
- have liver problems
- have kidney problems

- are lactose intolerant or have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in ATIVAN.

**Other warnings you should know about:**

**Severe Allergic Reactions:** Taking ATIVAN can cause severe allergic reactions that can lead to death. For symptoms of severe allergic reactions, see the **Serious side effects and what to do about them** table (below).

**Driving and Using Machines:** ATIVAN may affect your ability to be alert. Do NOT drive or operate machinery while you are taking ATIVAN:

- until you know how ATIVAN affects you
- for the first few days after you start or change dose
- If you are taking an opioid or drink alcohol

**Addiction, Abuse and Misuse:** Taking ATIVAN can lead to physical dependence, abuse and misuse, even if you take it as directed. See the **Serious Warnings and Precautions** box (above).

**Behavioural Problems:** Changes in thinking and behaviour may happen when you take ATIVAN. This can include aggressiveness, extroversion, confusion, strange behaviour, restlessness, illusions, hallucinations, feeling like you are not yourself, worsening of insomnia or worsening of depression including suicidal thinking. If you develop any unusual or disturbing thoughts or behavior while taking ATIVAN, talk to your healthcare professional immediately.

**Pregnancy:** Do not take ATIVAN if you are pregnant. ATIVAN may harm your unborn baby. It may also cause side effects and withdrawal symptoms in your baby after birth. Talk to your healthcare professional if you think you are pregnant or become pregnant while taking ATIVAN.

**Breastfeeding:** ATIVAN passes into breast milk. You should not breastfeed while taking ATIVAN. Talk to your healthcare professional about the best way to feed your baby while you are taking ATIVAN.

**Withdrawal:** If you suddenly stop your treatment, lower your dose too fast, or switch to another medication, you can experience withdrawal symptoms that can range from mild symptoms to severe or life threatening. Some of your withdrawal symptoms can last for months after you stop ATIVAN.

Your risk of going through withdrawal is higher if you are taking ATIVAN for a long time or at high doses. However, symptoms can still occur if you are taking ATIVAN as directed for a short period of time or slowly reducing the dose.

The symptoms of withdrawal often resemble the condition that you are being treated for. After stopping your treatment, it may be hard to tell if you are experiencing withdrawal or a return of your condition (relapse).

Tell your healthcare professional **right away** if you experience any symptoms of withdrawal after changing or stopping your treatment.

Severe symptoms of withdrawal include:

- feeling like you cannot move or respond (catatonia)
- severe confusion, shivering, irregular heart rate and excessive sweating (delirium tremens)
- feeling depressed
- feeling disconnected from reality (dissociation)
- seeing or hearing things that are not there (hallucinations)
- overactive behavior and thoughts (mania)
- believing in things that are not true (psychosis)
- convulsions (seizures), including some that do not stop
- thoughts or actions of suicide

For other symptoms of withdrawal, see the **Serious side effects and what to do about them** table (below).

To reduce your chances of going through withdrawal:

- always contact your healthcare professional before stopping or reducing your dose of ATIVAN or changing medications
- always follow your healthcare professional's instructions on how to reduce your dose carefully and safely
- tell your healthcare professional **right away** if you experience any unusual symptoms after changing or stopping your treatment

**ATIVAN with Opioids:** Taking ATIVAN with opioid medicines can cause severe drowsiness and breathing problems.

Tell your healthcare professional if you:

- are taking opioid medicines
- are prescribed an opioid medicine after you start taking ATIVAN

**Falls and Fractures:** Benzodiazepines like ATIVAN can cause you to feel sleepy, dizzy and affect your balance. This increases your risks of falling, which can cause fractures or other fall related-injuries, especially if you:

- take other sedatives
- drink alcohol
- are elderly or
- have a condition that causes weakness or frailty

**Blood Tests:** ATIVAN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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

### Serious Drug Interactions

Taking ATIVAN and opioids may cause:

- severe drowsiness
- trouble breathing
- coma
- death

### The following may interact with ATIVAN:

- medicines used to treat anxiety and insomnia
- sedative/hypnotics (sleeping pills)
- monoamine oxidase inhibitors (MAOIs) and other antidepressants
- medicines used to treat mental health problems such as haloperidol, clozapine
- narcotic analgesics (pain relievers, opioids), see **Serious Warnings and Precautions** box (above)
- allergy medication
- medicines used to prevent seizures such as valproate
- anesthetics, used during surgery
- probenecid, used to treat gout
- medicines used to treat breathing problems such as theophylline, aminophylline

**Do not take ATIVAN if you drink alcohol.**

### How to take ATIVAN:

- Always take ATIVAN exactly as your healthcare professional tells you to. Your healthcare professional will prescribe the dose that is right for you depending on your medical condition and how you respond to ATIVAN.
- Do not change your dose without talking to your healthcare professional.
- Your healthcare professional will tell you when to stop taking ATIVAN. Always follow your healthcare professional's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.
- If you were prescribed ATIVAN sublingual tablets:
  - Place the sublingual tablet under your tongue
  - It will dissolve in approximately 20 seconds
  - Do not swallow for at least 2 minutes to allow the medicine to absorb

### Usual adult dose:

**Anxiety problems:** 2 - 3 mg per day, in divided doses. Maximum: 6 mg per day.

**Before surgery:** Your healthcare professional will decide on the dose that is best for you based on your weight.

If you are 65 years of age or older you may be more sensitive to the effects of ATIVAN. Your healthcare professional might prescribe you a lower dose.

**Overdose:**

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

**Missed Dose:**

If you miss a dose of ATIVAN, contact your healthcare professional for instructions.

**What are possible side effects from using ATIVAN?**

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

Side effects may include:

- drowsiness
- dizziness
- confusion
- weakness and unsteadiness
- falls and fractures
- memory loss

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	
<b>UNCOMMON</b>			
<b>Behavioural Problems:</b> aggression, rage, sudden anxiety or excitation; restlessness, agitation, irritability; hallucinations (see or hear things that are not there) or delusions; severe sleep disturbances, nightmares, inappropriate behavior		√	
<b>Severe Allergic Reactions:</b> red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes, nausea, vomiting			√
<b>Myasthenia Gravis:</b> muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing			√

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	
<b>Liver Problems:</b> abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine		√	
<b>RARE</b>			
<b>Depression:</b> difficulty sleeping, changes in 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		√	
<b>UNKNOWN</b>			
<b>Overdose:</b> extreme sleepiness, confusion, slurred speech, slow reflexes, slow shallow breathing, coma, loss of balance and coordination, uncontrolled rolling of the eyes, low blood pressure			√
<b>Respiratory Depression:</b> slow, shallow or weak breathing			√
<b>Withdrawal:</b> <b>Severe symptoms include:</b> <b>Catatonia:</b> feeling like you cannot move or respond <b>Delirium Tremens:</b> severe confusion, shivering, irregular heart rate and excessive sweating <b>Feeling depressed</b> <b>Dissociation:</b> feeling disconnected from reality <b>Hallucinations:</b> seeing or hearing things that are not there <b>Mania:</b> overactive behaviour and thoughts <b>Psychosis:</b> Believing in things that are not true		√	

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	
<p><b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking</p> <p><b>Thoughts or actions of suicide</b></p> <p><b>Other symptoms include:</b></p> <p>Stomach and muscle cramps; trouble remembering or concentrating; diarrhea; feeling uneasy or restless; severe anxiety or panic-attacks; headache; sensitivity to light, noise or physical contact; shaking; vomiting; trouble sleeping; feeling irritable; muscle pain or stiffness; a burning or prickling feeling in the hands, arms, legs or feet; sweating</p>			

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.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 controlled room temperature (15 -30°C).

Sublingual tablets should also be protected from light.



Keep out of reach and sight of children.

**If you want more information about ATIVAN:**

- 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/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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