

## PATIENT MEDICATION INFORMATION

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

#### PRO-BUSPIRONE

#### Buspirone Hydrochloride Tablets, USP

Read this carefully before you start taking **PRO-BUSPIRONE** 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-BUSPIRONE**.

#### Serious Warnings and Precautions

**Addiction, Abuse and Misuse:** Even if you take PRO-BUSPIRONE exactly as you were told to, you are at risk for abuse, misuse, addiction, physical dependence and withdrawal. Abuse and misuse can result in overdose or death, especially if you take PRO-BUSPIRONE with:

- opioids
- alcohol or
- illicit drugs

Your doctor should:

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

Store PRO-BUSPIRONE in a secure place to avoid theft or misuse.

Withdrawal: If you suddenly stop taking PRO-BUSPIRONE, 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 doctor before stopping, or lowering your dose of BUSPIRONE or changing your medicine.

PRO-BUSPIRONE with Opioids: Taking PRO-BUSPIRONE with opioid medicines can cause:

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

#### What is PRO-BUSPIRONE used for?

PRO-BUSPIRONE is used for the short-term relief of anxiety symptoms in adults with Generalized Anxiety Disorder. Do not use PRO-BUSPIRONE long term.

| If you are 65 years or older, talk to your doctor before starting PRO-BUSPIRONE. PRO-BUSPIRONE may not

| be an effective treatment for you and you may be more sensitive to experiencing side effects.

### **How does PRO-BUSPIRONE work?**

PRO-BUSPIRONE belongs to a group of medicines called anxiolytics. These medicines change the levels of chemicals in the brain, which can help make you feel less anxious.

### **What are the ingredients in PRO-BUSPIRONE?**

Medicinal ingredients: Buspirone hydrochloride

Non-medicinal ingredients: Colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

### **PRO-BUSPIRONE comes in the following dosage forms:**

Tablets 5 mg and 10 mg

### **Do not use PRO-BUSPIRONE if:**

- you are allergic to buspirone hydrochloride or any ingredient in PRO-BUSPIRONE
- you have severe liver or kidney problems
- you are taking, or have taken within the past 14 days, a monoamine oxidase (MAO) inhibitor medication (such as methylene blue and linezolid)

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

- have taken benzodiazepines
- have or had liver or kidney problems
- are pregnant or trying to become pregnant
- are breastfeeding
- are 65 years of age or older
- are allergic to lactose
- 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)

### **Other warnings you should know about:**

**Extrapyramidal symptoms:** BUSPIRONE may cause extrapyramidal symptoms. Symptoms include tremors, slurred speech, muscle spasm of the neck, shoulders or body, restlessness, and rigid muscles.

**Serotonin toxicity (also known as Serotonin syndrome):** PRO-BUSPIRONE can cause serotonin toxicity, 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-BUSPIRONE 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.

**Driving and using machines:** PRO-BUSPIRONE may make you feel dizzy. Do not drive or do tasks that need special attention until you know how you respond to PRO-BUSPIRONE.

**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 BUSPIRONE.

Your risk of going through withdrawal is higher if you are taking PRO-BUSPIRONE for a long time or at high doses. However, symptoms can still occur if you are taking PRO-BUSPIRONE 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 doctor **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 heartrate 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 doctor before stopping or reducing your dose of PRO-BUSPIRONE or changing medications
- always follow your doctor's instructions on how to reduce your dose carefully and safely
- tell your doctor right away if you experience any unusual symptoms after changing or stopping your treatment

**PRO-BUSPIRONE with Opioids:** Taking PRO-BUSPIRONE with opioid medicines can cause severe drowsiness and breathing problems.

Tell your doctor if you:

- are taking opioid medicines
- are prescribed an opioid medicine after you start taking PRO-BUSPIRONE

Do NOT drive or operate heavy machinery or do tasks that require special attention until you know how taking an opioid medicine and BUSPIRONE affects you.

**Falls and Fractures:** Benzodiazepines like BUSPIRONE 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
- consume alcohol
- are elderly or
- have a condition that causes weakness or frailty

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

**The following may interact with PRO-BUSPIRONE:**

#### **Serious Drug Interactions**

Taking PRO-BUSPIRONE and opioids may cause:

- severe drowsiness
- trouble breathing
- coma
- death

- Food
- Medicines used to treat depression such as serotonergic agents, monoamine oxidase inhibitors and trazodone
- Medicines used to treat mental health problems such as haloperidol, diazepam, and nefazodone
- Medicines used to treat high blood pressure such as propranolol, diltiazem and verapamil
- Medicine used to prevent blood clots called warfarin
- Medicine used to treat heart failure called digoxin
- Medicines used to treat infections such as erythromycin, rifampicin, ketoconazole and itraconazole
- Medicine used to treat HIV called ritonavir
- Medicine used to treat inflammation called dexamethasone
- Medicines used to treat epilepsy such as phenytoin, phenobarbital, and carbamazepine
- Medicine used to treat ulcers called cimetidine
- Grapefruit or grapefruit juice
- Alcohol. Do not drink alcohol while taking this medication.

**How to take PRO-BUSPIRONE:**

- Take PRO-BUSPIRONE exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

**Usual dose:**

- The starting adult dose is 5 mg two to three times a day.
- Based on your response and tolerability, your healthcare professional may increase your dose.
- The usual adult dose is 20 mg to 30 mg in two to three divided doses. If you have liver or kidney problems, your doctor may prescribe you a lower dose.
- The maximum daily adult dose is 45 mg. Do not increase the prescribed dose of BUSPIRONE unless told to by your healthcare professional.
- Your doctor will slowly decrease your dose and will tell you when to stop taking the medicine. Always follow your doctor's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.

**Overdose:**

Signs of an overdose include:

- drowsiness,
- difficulty balancing and speaking,
- nausea and vomiting,
- dizziness,
- clammy feeling,
- trouble thinking,
- feeling pleasure or excitement,
- upset stomach or indigestion,
- headache,
- itching,
- narrowing eye pupil,
- low blood pressure,
- tremor,
- incoordination,
- difficulty sleeping (insomnia) and
- seeing or believing things that are not there (hallucinations).

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

**Missed Dose:**

If you have forgotten to take your dose, carry on and take your next dose at the usual time. Do not try to make up for a missed dose by taking a double dose the next time.

**What are possible side effects from using PRO-BUSPIRONE?**

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

Side effects may include:

- Falls and fractures
- Sweating and clamminess
- Dry mouth
- Constipation
- Diarrhea
- Being sick (vomiting)
- Dizziness
- Headache
- Nervousness
- Light-headedness
- Nausea
- Muscle aches, pain, cramps or spasms
- Frequent urination at night (nocturia) or bed-wetting (enuresis)
- Ringing, buzzing clicking or hissing in the ears (tinnitus)
- Rash or itchiness
- Eye problems such as sore eyes, pressure on eyes, blurred vision, red or itchy eyes
- Irregular menstruation, missing one or more menstrual period
- Decreased or increased sexual desire
- Delayed ejaculation or impotence
- Stiff neck or jaw

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>VERY COMMON</b>			
Chest pain		√	
<b>Tachycardia</b> (abnormally fast heartbeat): dizziness, light headedness, shortness of breath, racing heart		√	
<b>COMMON</b>			
<b>Syncope</b> (fainting): a temporary loss of consciousness due to a sudden drop in blood pressure		√	
<b>Eosinophilia</b> (increased numbers of certain white blood cells): abdominal pain, rash, weight loss, wheezing.		√	
Rectal bleeding: black, tarry stool, blood in the stool		√	
<b>Skin problems:</b> Easy bruising, a painful skin condition where fluid fills a space between layers of skin (blisters)		√	

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>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
<b>Hypertension</b> (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish color to your lips and skin, racing pulse or heart palpitations		✓	
<b>Arthralgia</b> : joint pain		✓	
<b>Skin problems</b> : Easy bruising, a painful skin condition where fluid fills a space between layers of skin (blisters)		✓	
<b>RARE</b>			
<b>Congestive Heart Failure</b> (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			✓
<b>Myocardial infarction</b> (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			✓
<b>Cardiomyopathy</b> (signs of heart muscle disease): breathlessness or swelling of the legs			✓
<b>Bradycardia</b> (abnormally slow heartbeat)			✓
<b>Thyroid gland problems</b> : body aches, fatigue, low blood pressure, light-headedness, loss of body hair, skin discoloration, unexplained weight loss		✓	
<b>Stroke</b> : Sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body; sudden confusion, difficulty speaking or understanding others; sudden difficulty in walking or loss of balance or coordination; suddenly feeling dizzy or sudden severe headache with no known cause.			✓

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>Serotonin toxicity:</b> a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38 °C), or rigid muscles.		√	
<b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat		√	
<b>Leukopenia</b> (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms		√	
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
<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, and low blood pressure.		√	
<b>Respiratory Depression:</b> slow, shallow or weak 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>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 <b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking <b>Thoughts or actions of suicide</b> <b>Other symptoms include:</b> Stomach 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.		√	

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 room temperature (15°C-30°C) in tight, light-resistant containers. Medicines should not be disposed of via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment. Keep out of reach and sight of children.

**If you want more information about PRO-BUSPIRONE:**

- 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>); or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca)

This leaflet was prepared by Pro Doc Ltée.  
Laval, Quebec, H7L 3W9

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