PART III: CONSUMER INFORMATION

PRO-ALPRAZOLAM
and
PRO-ALPRAZOLAM TS
Alprazolam Tablets USP

This leaflet is part III of a three-part "Product Monograph" published when **PRO-ALPRAZOLAM** and **PRO-ALPRAZOLAM TS** (alprazolam tablets) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **PRO-ALPRAZOLAM** and **PRO-ALPRAZOLAM TS**. Contact a member of your healthcare team if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-ALPRAZOLAM has been prescribed to you by your doctor to relieve your symptoms of the following conditions:

- Generalized anxiety disorder (excessive anxiety or worry)
- Panic disorder (repeated, unexpected panic attacks of extreme fear and worry about these attacks)

If you are 65 years or older, talk to your doctor before starting PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS. PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS may not be an effective treatment for you and you may be more sensitive to experiencing side effects.

What it does:
PRO-ALPRAZOLAM contains the active ingredient alprazolam, which belongs to a group of medicines known as benzodiazepines. PRO-ALPRAZOLAM has sedative properties which help in the treatment of anxiety and panic.

When it should not be used:
Do not take PRO-ALPRAZOLAM if you:

- are allergic to the group of medicines known as benzodiazepines (examples: clonazepam, chlordiazepoxide, diazepam, or flurazepam).
- are allergic to PRO-ALPRAZOLAM or any of the ingredients listed in the section "**What the nonmedicinal ingredients are**".
- have acute narrow angle glaucoma, a condition associated with increased pressure in the eye that may cause loss of sight.
- have myasthenia gravis, a chronic disease characterized by weakness of the skeletal muscles.
- have a liver condition.
- have lung disease or breathing problems.
- have a sleep disorder that causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- are taking ketoconazole (eg., Nizoral) or itraconazole (eg., Sporanox), medicines used to treat fungal infections.

PRO-ALPRAZOLAM should not be used in patients under 18 years of age.

What the medicinal ingredient is:
Alprazolam

What the nonmedicinal ingredients are:
All tablets contain ingredients croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose. The 0.5 mg tablet also contains FD&C yellow #6. The 1 mg tablet also contains D&C red #30 and FD&C blue #2

What dosage forms it comes in:
PRO-ALPRAZOLAM 0.25 mg tablet: oval, white, biconvex tablet, are side scored and engraved "ALP" over ".25" one side, other side plain.

PRO-ALPRAZOLAM 0.5 mg tablet: oval, peach, biconvex tablet, are side scored and engraved "ALP" over "0.5" one side, other side plain.

PRO-ALPRAZOLAM 1 mg tablet: oval, lavender, biconvex tablet, scored and engraved "ALP" over "1" one side, and plain on the other side.

PRO-ALPRAZOLAM TS 2 mg tablet: white, rectangular, triscored tablets and engraved "APO 2" on one side, triscored and plain on the other. This can be broken into 4 individual 0.5 mg segments.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Addiction, Abuse and Misuse: Even if you take PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS as prescribed, you are at risk for abuse, misuse and addiction. This can result in overdose or death, especially if it is taken with:

- **opioids**
- **alcohol or**
- **illicit drugs**

Your doctor should:

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

Store PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS in a secure place to avoid theft or misuse.

Withdrawal: If you suddenly stop taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS, lower your dose too fast, or switch to another medication, you can experience severe or life-threatening withdrawal symptoms (see the withdrawal section below).

Always contact your doctor before stopping or lowering your dose of PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS or changing your medicine.

PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS with Opioids: Taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS with opioid medicines can cause:

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

Withdrawal

Always contact your doctor before stopping or reducing your dosage of PRO-ALPRAZOLAM. 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 PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS.

Your risk of going through withdrawal is higher if you are taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS for a long time or at high doses. However, symptoms can still occur if you are taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS 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

Therefore, always follow the treatment as prescribed by your doctor.

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-ALPRAZOLAM and PRO-ALPRAZOLAM TS 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

Dependence

Benzodiazepines such as PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS have caused dependence (addiction) and withdrawal symptoms can occur when treatment is stopped suddenly. The risk of dependence (addiction) increases with higher doses and longer duration of treatment, or after suddenly stopping treatment.

BEFORE you use PRO-ALPRAZOLAM talk to your doctor or pharmacist 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, liver or kidney condition.
- have a history of alcohol or drug abuse.
- have a history of depression and/or suicide attempts.
- are pregnant, think you may be pregnant, or are planning to become pregnant.
- are breast feeding.
- regularly drink alcohol.
- have lactose intolerance.

Mental alertness

PRO-ALPRAZOLAM can cause drowsiness and affect your ability to be alert. You should not perform activities that require mental alertness such as driving or operating machinery until you know how this drug will affect you. This effect of PRO-ALPRAZOLAM may be made worse if you take alcoholic drinks. If your doctor has increased your dose or if you have changed the timings of when you take your medication this may also change how the drug affects you.

Risk of memory loss

Memory loss has been reported. This has occurred in people taking the usual doses.

Falls and Fractures: Benzodiazepines like PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS can cause you to feel sleepy, dizzy and affect your balance. This increases the 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

Worsening of side effects with alcohol and other drugs
PRO-ALPRAZOLAM may have more pronounced sedative effects when taken with alcohol or other drugs that can make you sleep, such as: narcotic pain relievers, sleeping pills, antihistamines, medications to control seizures, antidepressants or antipsychotics. **Do not** take PRO-ALPRAZOLAM if you drink alcohol. **Do not** use PRO-ALPRAZOLAM with these other medications without first discussing with your doctor.

PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS with Opioids: Taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS 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 your start taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS

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

Pregnancy
Some benzodiazepines have been linked to birth defects when taken during the early months of pregnancy. Babies born to mothers who have taken benzodiazepines during the last weeks of pregnancy or during labour have been known to have overly relaxed muscles and breathing problems, and may also have withdrawal symptoms after birth.

Do not take this medicine if you are pregnant (or think you may be pregnant), unless advised by your doctor. Consult with your doctor before taking PRO-ALPRAZOLAM if you are planning to become pregnant.

Breast feeding
PRO-ALPRAZOLAM may pass into breast milk. Therefore, if you are breast feeding, this medicine should be avoided.

INTERACTIONS WITH THIS MEDICATION

Serious Drug Interactions

Taking PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS and opioids may cause:

- **severe drowsiness**
- **trouble breathing**
- **coma**
- **death**

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food store without a prescription.

PRO-ALPRAZOLAM may have more pronounced side effects when taken with alcohol or other drugs that affect the central nervous system. **Do not** drink alcohol while taking PRO-ALPRAZOLAM. **Do not** use PRO-ALPRAZOLAM with the following other medicines without first discussing with your doctor:

- narcotic pain relievers (opioids, e.g., morphine, codeine) (see **Serious Warnings and Precautions box**)
- sleeping pills
- antihistamines (medicines used for relief of allergy symptoms)
- anticonvulsants (medications used to control seizures)
- antidepressants (medicines used to treat anxiety or depression)
- antipsychotics (medicines used to treat mental illnesses such as schizophrenia)

PRO-ALPRAZOLAM should not be taken with ketoconazole or itraconazole (medicines used to treat fungal infections) because these medicines can cause an increase in the amount of PRO-ALPRAZOLAM in your blood and can enhance side effects.

Other medicines that can affect the amount of PRO-ALPRAZOLAM in your blood include cimetidine, fluvoxamine, carbamazepine, HIV protease inhibitors, and birth control pills.

Talk to your doctor if you are using PRO-ALPRAZOLAM with digoxin, as PRO-ALPRAZOLAM may affect the amount of digoxin in your blood.

Always tell your doctor about any other medicines you are taking or plan to take.

PROPER USE OF THIS MEDICATION

Always take the tablets exactly as your doctor tells you to. Your doctor will prescribe a suitable dose for you. The dose your doctor prescribes will depend on your illness and how you respond to the medicine. The table below shows the different doses that your doctor may prescribe according to your illness.

Usual Daily Dose

	Usual Daily Dose
Anxiety disorders	0.25 mg, two to three times per day. Maximum 3 mg/day.
Panic disorders	0.5 mg, three times per day. Maximum 10 mg/day.

The total daily dose should be taken as advised by your doctor.

Do not change the prescribed dose yourself.
If you think the effect of your medicine is too weak or too strong, talk to your doctor.

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.

Because elderly patients can be more sensitive to the effects of PRO-ALPRAZOLAM, lower doses may be prescribed.

Overdose:

Contact your doctor, regional Poison Control Centre or pharmacist immediately if you suspect you have taken an overdose or someone else accidentally takes your PRO-ALPRAZOLAM. If you are unable to contact them, go to a hospital emergency department for medical help, even though you may not feel sick. Show the doctor your bottle of tablets.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications PRO-ALPRAZOLAM can cause some side effects. For most patients, these side effects are likely to be minor and temporary as your body adjusts to the medicine. However, some may be serious. Consult your doctor or pharmacist as soon as you can if you do not feel well while taking PRO-ALPRAZOLAM.

The most common side effects are:

- Feeling drowsy or tired, especially at the start of treatment.
- Dizziness
- Loss of some balance and coordination
- Falls and fractures
- Memory problems
- Constipation
- Slurred speech

Less common possible side effects are:

- Agitation
- Changes in sex drive (increased or decreased)
- Changes in weight (gain or loss)
- Increased appetite
- Difficulty urinating
- Bladder control problems

In rare cases, PRO-ALPRAZOLAM can affect liver function, and disorders such as hepatitis or liver failure may occur. Your doctor will monitor your blood for effects of PRO-ALPRAZOLAM on your liver.

Elderly patients may be especially susceptible to side effects. Excessive drowsiness or loss of balance may increase the risk of falls and fractures in elderly patients.

All patients should be cautious about performing hazardous activities that require complete mental alertness, such as operating machinery or driving a car.

Withdrawal-related side effects:
If treatment is stopped suddenly or there is a large decrease in dose, symptoms of withdrawal may occur, including: restlessness and trouble sleeping. In severe cases of withdrawal, symptoms may include: irritability, nervousness, trouble sleeping, diarrhea, stomach pains, vomiting, sweating, tremors, numbness and tingling of the extremities, hallucinations (seeing or hearing things that are not there), being unusually sensitive to light, noise and physical contact and seizures.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
Rare	Unusual behavioural problems (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 behaviour		√	
	Allergic reactions (red skin, skin rashes, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath)			√
	Depression. Symptoms may include: 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		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
	Hepatitis, liver failure (yellow skin and eyes, nausea, vomiting, pain in upper right abdomen, loss of appetite, dark colored urine)			√
	Serious skin reactions (rash that may be severe, red skin, blistering of the lips, eyes or mouth, peeling skin)			√
	Increased pressure in the eyes (change in side vision, sudden severe pain in the eye, decreased or cloudy vision, seeing rainbow-like halos around lights, eyes feeling swollen)			√
Un-known	**Overdose:** 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.			√
	Respiratory Depression: slow, shallow or weak breathing.			√
	Withdrawal: **Severe symptoms include:** Catatonia: feeling like you cannot move or respond **Delirium Tremens:** severe confusion, shivering, irregular heartrate and excessive sweating **Feeling depressed** **Dissociation:** feeling disconnected from reality **Hallucinations:** seeing or hearing things that are not there		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
	Mania: overactive behaviour and thoughts **Psychosis:** believing in things that are not true Convulsions: (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking **Thoughts or actions of suicide** **Other symptoms include:** 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.			

This is not a complete of side effects. For any unexpected effects while taking PRO-ALPRAZOLAM, contact your doctor or pharmacist.

HOW TO STORE IT

PRO-ALPRAZOLAM should be stored at room temperature (15ºC to 30ºC).

Keep out of reach and sight of children.

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.

MORE INFORMATION

If you want more information about PRO-ALPRAZOLAM and PRO-ALPRAZOLAM TS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Part III: Consumer Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html). Find the Consumer Information by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca

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