IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PRO-LORAZEPAM
Oral Tablets

This leaflet is part III of a three-part "Product Monograph" published for PRO-LORAZEPAM and is designed specifically for Consumers.

Please read this information before you start to take your medicine. Keep this leaflet until you have finished all your tablets, as you may need to read it again. If you are helping someone else to take PRO-LORAZEPAM, read this leaflet before you give the first tablet.

This leaflet is a summary and will not tell you everything about PRO-LORAZEPAM. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

PRO-LORAZEPAM is useful for the short-term relief of manifestations of severe anxiety in people with anxiety neurosis.

PRO-LORAZEPAM are not recommended for mild to moderate anxiety and tension associated with the stresses of everyday life.

What it does:
PRO-LORAZEPAM are benzodiazepines with sedative properties which help in the treatment of anxiety.

When it should not be used:
- If you are allergic to the group of medicines known as benzodiazepines (examples: diazepam, clonazepam, chlordiazepoxide, bromazepam, or flurazepam)
- If you are allergic to any of the ingredients it contains (see '**What the nonmedicinal ingredients are**')
- If you have myasthenia gravis, a chronic disease characterized by weakness of the skeletal muscles.
- If you have acute narrow angle glaucoma (a disease of the eye which causes progressive vision loss).

What the medicinal ingredient is:
Lorazepam.

What the nonmedicinal ingredients are:
PRO-LORAZEPAM oral tablets: Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium and Magnesium Stearate.

What dosage forms it comes in:
0.5, 1 and 2 mg oral tablets.

WARNINGS AND PRECAUTIONS

- **Severe anaphylactic/anaphylactoid allergic reactions have been reported with the use of benzodiazepines. Cases of angioedema (swelling inside the mouth and throat) involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of benzodiazepines. Some patients taking benzodiazepines have had additional symptoms such as dyspnea (difficult respiration), throat closing, or nausea and vomiting. Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with a benzodiazepine should not re-start the drug.**
- **PRO-LORAZEPAM** may affect your ability to be alert. Driving, operating machinery and other hazardous activities should therefore be avoided altogether or at least during the first few days of treatment. This effect of **PRO-LORAZEPAM** 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 modify your reactions.
- You must not consume alcohol or other drugs that affect the central nervous system while taking **PRO-LORAZEPAM** (see **INTERACTIONS WITH THIS MEDICATION** below).
- Benzodiazepines such as **PRO-LORAZEPAM** have produced 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.
- Always contact your doctor before stopping or reducing your dosage of **PRO-LORAZEPAM**, as suddenly stopping treatment or a large decrease in dose can cause withdrawal symptoms (See Withdrawal-related side effects in the section **SIDE EFFECTS AND WHAT TO DO ABOUT THEM** below).
- An increased risk of falls and fractures has been reported in elderly people who take benzodiazepines such as **PRO-LORAZEPAM**.
- Memory loss may occur when **PRO-LORAZEPAM** is used at therapeutic doses.
- A variety of abnormal thinking and behaviour changes may occur when you use a benzodiazepine, including aggressiveness, extroversion, confusion, strange behaviour, restlessness, illusions, hallucinations, feeling like you are not yourself, worsening of insomnia or worsening of depression including suicidal thinking. It is rarely clear whether such symptoms are caused by the medication, by an illness that was present before the medication was used or are simply spontaneous happenings. If you develop any unusual or disturbing thoughts or behavior while using **PRO-LORAZEPAM**, discuss the matter immediately with your doctor.
- **PRO-LORAZEPAM** are not recommended for use in depressive neurosis or in psychotic reactions.
- Certain benzodiazepines have been linked to birth defects when taken during the early months of pregnancy. In addition, benzodiazepines taken during the last weeks of pregnancy have been known to sedate the baby and may also cause withdrawal symptoms after birth. Do not take this medicine if you are pregnant, or might become pregnant, unless advised by your doctor. Contact your doctor if you think you may be pregnant, or are intending to become pregnant.
- **PRO-LORAZEPAM** pass into breast milk. Therefore, if you are breast feeding, this medicine should be avoided. Your doctor will discuss this with you.

BEFORE you use talk to your doctor or pharmacist if:

- You have lung disease or breathing problems (e.g. chronic obstructive pulmonary disease (COPD), sleep apnea syndrome)
- You have a history of depression, suicide attempts or psychosis
- You regularly drink alcohol or use recreational drugs or have a history of dependence /addiction to alcohol or drugs.
- You have liver disease
- You have kidney disease
- You are pregnant or plan on becoming pregnant
- You are breastfeeding

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription and herbal products.

Drugs that may interact with PRO-LORAZEPAM include:

- barbiturates
- antipsychotics
- sedative/hypnotics (sleeping pills)
- anxiolytics
- antidepressants
- antipsychotics (including Haloperidol, Clozapine)
- narcotic analgesics (pain relievers)
- sedative antihistamines (allergy medications)
- anticonvulsants (including Valproate)
- anesthetics
- Probenecid (to reduce uric acid levels)
- Theophylline or aminophylline (respiratory treatments)
- Alcohol

Do not take PRO-LORAZEPAM if you drink alcohol.
Do not use **PRO-LORAZEPAM** along with other medications without first discussing this with your doctor.

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
Generalized anxiety disorders	0.5 to 2 mg, two to three times per day. Maximum 6 mg/day.
Excessive Anxiety Prior to Surgical Procedures	0.05 mg/kg 1 to 2 hours before surgery. Maximum 4 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.

Do not take **PRO-LORAZEPAM** if it is not prescribed for you. Your doctor will advise you when to stop taking the medicine. Your doctor will slowly decrease the dosage as sudden discontinuation of treatment can cause the appearance of withdrawal symptoms.

Because elderly patients can be more sensitive to the effects of **PRO-LORAZEPAM** and **PRO-LORAZEPAM Sublingual**, lower doses may be prescribed.

PRO-LORAZEPAM are not for use in children under 18 years of age.

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-LORAZEPAM**. 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.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The adverse reaction most frequently reported for **PRO-LORAZEPAM** and **PRO-LORAZEPAM Sublingual** was drowsiness. Dizziness, weakness and unsteadiness were also common.

Release of hostility and other paradoxical effects such as irritability and excitability, are known to occur with the use of benzodiazepines. Please tell your doctor right away if you feel these effects when taking **PRO-LORAZEPAM**. Paradoxical reactions may be more likely to occur in children or the elderly. In addition, hypotension (low blood pressure), mental confusion, slurred speech, over sedation and abnormal laboratory test results indicating changes in the liver, kidney and blood cells have been reported with these drugs.

If you develop symptoms of myasthenia gravis or the symptoms of your existing myasthenia gravis worsen, tell your doctor right away. These symptoms could include muscle weakness that gets worse with activity and gets better with rest, drooping eyelid, blurred or double vision, difficulty chewing and swallowing, or trouble breathing.

Withdrawal-related side effects:

- With sudden discontinuation of treatment with **PRO-LORAZEPAM** symptoms of withdrawal may occur, including: headache, muscle pain, convulsions, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases of withdrawal, symptoms may include numbness and tingling of the extremities, hallucinations, increased sensitivity to light, noise and physical contact and seizures.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

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Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency help
		Only if severe	In all cases	
Uncommon	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 behavior		√	
	Anaphylactic /anaphylactoid reactions, severe allergic reactions (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)			√
Uncommon	Myasthenia gravis (muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing)			√
	Liver disorder (symptoms include abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine)		√	
Rare	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.		√	

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

HOW TO STORE IT

PRO-LORAZEPAM oral tablets: Store at room temperature 15-30°C (59-86°F). Protect from moisture.

Keep out of reach and out of sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345, or
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanda.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

IMPORTANT: PLEASE READ

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else, even if you think they have the same symptoms that you have, as it may harm them. If you have any further questions, please ask your doctor or pharmacist.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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