PART III: CONSUMER INFORMATION

BROMAZEPAM – 3
BROMAZEPAM - 6
bromazepam tablets

This leaflet is a part of the "Product Monograph" published for BROMAZEPAM 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 BROMAZEPAM, read this leaflet before you give the first tablet.

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

ABOUT THIS MEDICATION

What the medication is used for:
The short-term treatment of severe anxiety.

What it does:
BROMAZEPAM contains the active ingredient bromazepam, which belongs to a group of medicines known as benzodiazepines. BROMAZEPAM has sedative properties which help in the treatment of severe anxiety.

When it should not be used:

- If you are allergic to the group of medicines known as benzodiazepines (examples: clonazepam, chlordiazepoxide, diazepam, or flurazepam)
- If you are allergic to the medicinal ingredient (bromazepam)
- If you are allergic to any of the other non-medicincal ingredients it contains(see '**What the non-medicinal ingredients are**')
- If you suffer from lung disease or from sleep apnea.
- If you have a liver condition.
- If you have glaucoma.
- If you have myasthenia gravis.
- If a child is less than 18 years of age.

What the medicinal ingredient is:
Bromazepam.

What the important non-medicinal ingredients are:

Tablets 3 mg: D&C Red #30 Aluminum Lake 30%, D&C Red #7 Toner Calcium Lake 50%, lactose monohydrate, starch, magnesium stearate, microcrystalline cellulose.

Tablets 6 mg: Starch, D&C #10 Aluminum Lake 16%, ferric-ferrous oxide, Brilliant Blue FCF AL Lake 12%, magnesium stearate, lactose monohydrate, microcrystalline cellulose (PH102).

What dosage forms it comes in:
BROMAZEPAM is available as:

3 mg tablet- pink in colour, round, flat-faced, bevelled edge, scored tablet (engraved PRO over B-3 on one side).

6 mg tablet - green in colour, round, flat-faced, bevelled edge, scored tablet (engraved PRO over B-6 on one side).

WARNINGS AND PRECAUTIONS

- BROMAZEPAM 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 BROMAZEPAM 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 your central nervous system while taking BROMAZEPAM (see INTERACTIONS WITH THIS MEDICATION below).
- Always contact your doctor before stopping or reducing your dosage of BROMAZEPAM, as suddenly stopping treatment or a large decrease in dose can cause withdrawal symptoms.
- Benzodiazepines such as BROMAZEPAM 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. Symptoms of withdrawal may include shaking, convulsions (seizures), sweating, sleep disturbances, agitation/restlessness, headache, muscle pain, anxiety, confusion, and irritability. In severe cases of withdrawal, symptoms may include numbness and tingling of the extremities, hallucinations (see or hear things that are not there), increased sensitivity to light, noise and physical contact and seizures.
- There have been reports of falls and fractures in people who take benzodiazepines such as BROMAZEPAM. The risk is increased in those also taking other sedatives (including alcoholic beverages) and in the elderly.
- Memory loss may occur when BROMAZEPAM is used at therapeutic doses.
- If you develop any unusual or disturbing thoughts or behaviour while using BROMAZEPAM, discuss the matter immediately with your doctor.
- 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.

- BROMAZEPAM may 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 BROMAZEPAM talk to your doctor or pharmacist if you:

- Have a lung, liver or kidney condition.
- Are taking or plan on taking ANY other drugs (including herbal preparations, drugs you purchase without prescriptions, and those not prescribed by your doctor).
- Regularly drink alcohol or use recreational drugs or have a history of dependence /addiction to alcohol or drugs.
- Have a history of depression and/or suicide attempts.
- Have the rare hereditary problem of galactose intolerance.
- Are pregnant or plan to be pregnant.

INTERACTIONS WITH THIS MEDICATION

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.

Some medicines may interfere with BROMAZEPAM. These medicines include:

- medicines to control seizures
- narcotics and narcotic pain relievers
- muscle relaxants
- sleeping medication
- antihistamines or allergy medications
- medicines to treat your mood, such as monoamine oxidase inhibitors, tricyclic antidepressants, phenothiazines
- cimetidine or propranolol

These medicines may be affected by BROMAZEPAM or may affect how well BROMAZEPAM works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of the above, tell him/her before you start taking BROMAZEPAM.

You must not consume alcohol while taking BROMAZEPAM as its effects may worsen side effects that some patients experience with BROMAZEPAM.

PROPER USE OF THIS MEDICATION

Usual dose:

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 the nature of your illness, your reaction to the medicine, your age and body weight. The table below shows the different doses that your doctor may prescribe according to your age. Your doctor will start you on an initial low dose and gradually increase it until the desired effect is achieved.

	Usual Daily Dose
Adults	Depending upon severity of symptoms – 6 mg to 18 mg, in equally divided doses. Treatment may be initiated at a lower dose.
Elderly	Maximum of 3 mg in equally divided doses. Dose can be increased gradually as needed and tolerated.

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 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.

Overdose:

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

Like all medications BROMAZEPAM 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 BROMAZEPAM.

The most common side effects are:

- Feeling drowsy or tired, especially at the start of treatment.
- Loss of some muscle coordination
- Dizziness

Less common possible side effects are:

- Rash, nausea, headache, blurred vision, tremors, hypotension (low blood pressure), urinary incontinence, and constipation.
- In rare cases changes in your blood and liver may occur and your doctor will monitor for these.
- Falls and fractures: The risk is increased in those also taking other sedatives (including alcoholic beverages) and in the elderly.

Withdrawal-related side effects:

- With sudden discontinuation of treatment with BROMAZEPAM 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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek 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, 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)			✓ Immediately.
	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. If you are concerned about these or any other unwanted side-effects, talk to your doctor or pharmacist.

HOW TO STORE IT

- Keep BROMAZEPAM is a cool dry place stored at room temperature (15-30°C)
- Keep this medicine out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the 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
- 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.healthcanada.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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This document 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.

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

Last revised: November 7, 2014