PART III: CONSUMER INFORMATION

APO-ALPRAZ AND APO-ALPRAZ TS
(alprazolam tablets USP)

This leaflet is part III of a three-part "Product Monograph" published when **APO-ALPRAZ and APO-ALPRAZ 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 **APO-ALPRAZ and APO-ALPRAZ 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:
APO-ALPRAZ 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)

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

When it should not be used:
Do not take APO-ALPRAZ if you:

- are allergic to the group of medicines known as benzodiazepines (examples: clonazepam, chlordiazepoxide, diazepam, or flurazepam).
- are allergic to APO-ALPRAZ 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.

APO-ALPRAZ 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:
APO-ALPRAZ 0.25 mg tablet: oval, white, biconvex tablet, are side scored and engraved "APO" over ".25" one side, other side plain.
APO-ALPRAZ 0.5 mg tablet: oval, peach, biconvex tablet, are side scored and engraved "APO" over "0.5" one side, other side plain.
APO-ALPRAZ 1 mg tablet: oval, lavender, biconvex tablet, scored and engraved "APO" over "1" one side, and plain on the other side.
APO-ALPRAZ 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

Taking APO-ALPRAZ and APO-ALPRAZ TS with opioid medicines can cause severe drowsiness, breathing problems, coma, and death.

BEFORE you use APO-ALPRAZ talk to your doctor or pharmacist if you:

- 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
APO-ALPRAZ 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 APO-ALPRAZ 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 falls, memory loss
There have been reports of falls and fractures in people who take benzodiazepenes such as alprazolam. Memory loss has also

been reported. These have occurred in people taking the usual doses.

Worsening of side effects with alcohol and other drugs
APO-ALPRAZ 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 APO-ALPRAZ if you drink alcohol. **Do not** use APO-ALPRAZ with these other medications without first discussing with your doctor.

Withdrawal symptoms
Always contact your doctor before stopping or reducing your dosage of APO-ALPRAZ. Suddenly stopping treatment or a large decrease in dose can cause withdrawal symptoms. This can happen with drugs of this type even when taking for only a few weeks.

Symptoms of withdrawal may include mild symptoms, such as a feeling of dissatisfaction, restlessness or trouble sleeping.

In severe cases of withdrawal, symptoms may include irritability, nervousness, insomnia, agitation, diarrhea, stomach pains, vomiting, sweating, shaking, 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.
Therefore, always follow the treatment as prescribed by your doctor.

Dependence
Benzodiazepines such as alprazolam 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.

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 APO-ALPRAZ if you are planning to become pregnant.

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

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.

APO-ALPRAZ 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 APO-ALPRAZ. **Do not** use APO-ALPRAZ 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)

APO-ALPRAZ 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 APO-ALPRAZ in your blood and can enhance side effects.

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

Talk to your doctor if you are using APO-ALPRAZ with digoxin, as APO-ALPRAZ 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 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 APO-ALPRAZ, 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 APO-ALPRAZ. 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 APO-ALPRAZ 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 APO-ALPRAZ.

The most common side effects are:

- Feeling drowsy or tired, especially at the start of treatment.
- Dizziness
- Loss of some balance and coordination
- 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, APO-ALPRAZ can affect liver function, and disorders such as hepatitis or liver failure may occur. Your doctor will monitor your blood for effects of APO-ALPRAZ 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.

<u>Withdrawal-related side effects</u>:

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 with your doctor or pharmacist		Stop taking drug and seek emergency 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		*	
	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)			*

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

HOW TO STORE IT

APO-ALPRAZ should be stored at room temperature (15 ºC - 30ºC).

Keep out of the reach 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 APO-ALPRAZ and APO-ALPRAZ TS:

- 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.apotex.ca/products, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

Last revised: October 4, 2018