

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

 FLURAZEPAM – 15  
 FLURAZEPAM - 30

#### Flurazepam Hydrochloride Capsules USP

This leaflet is part III of a three-part "Product Monograph" published when FLURAZEPAM was approved for sale in Canada 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. This leaflet should not replace a discussion between you and your doctor about the risks and benefits of FLURAZEPAM. This leaflet is a summary and will not tell you everything about FLURAZEPAM. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

FLURAZEPAM is intended to help you sleep if you have transient and short-term insomnia. Symptoms of insomnia include difficulty falling asleep and/or waking up often during the night or too early in the morning.

Treatment with FLURAZEPAM should usually not go on for more than 7-10 days and should be restricted for insomnia where disturbed sleep results in impaired daytime functioning. FLURAZEPAM does not treat the underlying cause of your insomnia.

##### What it does:

FLURAZEPAM is one of several benzodiazepine sleeping pills that have generally similar properties such as a calming effect.

If you are prescribed one of these medications, you should consider both their benefits and risks. Important risks and limitations include the following:

- you may become dependent on the medication,
- the medication may affect your mental alertness or memory, particularly when not taken as prescribed. (see "WARNINGS AND PRECAUTIONS")

##### When it should not be used:

Do not take FLURAZEPAM if you have:

- known allergy to flurazepam or other benzodiazepines, or any of the ingredients FLURAZEPAM contains (see "What the nonmedicinal ingredients are")
- severe lung or respiratory disease, including sleep apnea
- myasthenia gravis, a chronic disease characterized by weakness of the skeletal muscles
- a severe liver condition

##### What the medicinal ingredient is:

Flurazepam hydrochloride

##### What the nonmedicinal ingredients are:

Non-medicinal ingredients are lactose, starch, stearic acid, gelatin, titanium dioxide, sodium lauryl sulfate, silicon dioxide, FD&C yellow #6, D&C yellow #10, FD&C red #40 (15 mg) and FD&C yellow #40 (30 mg).

##### What dosage forms it comes in:

FLURAZEPAM is available in 15 mg or 30 mg capsules for oral administration.

#### WARNINGS AND PRECAUTIONS

##### Complex sleep-related behaviours

There have been reports of people getting out of bed while not fully awake after taking FLURAZEPAM and doing activities that they did not know they were doing. The next morning, they did not remember doing those activities. This unusual behaviour is more likely to occur when FLURAZEPAM is taken with alcohol or other drugs that can make you sleepy such as those for the treatment of depression or anxiety. The activities you may do in these situations can put you and people around you in danger. Reported activities included driving a car ("sleep-driving"), leaving the house, making and eating food, talking on the phone, etc.

##### Important:

1. Do not take more FLURAZEPAM than prescribed.
2. Do not take FLURAZEPAM if you drink alcohol.
3. Talk to your doctor about all of your medicines, including over-the-counter medicines and herbal products. Your doctor will tell you if you can take FLURAZEPAM with your other medicines.
4. You and people close to you should watch for the type of unusual behaviour described above. If you find out that you have done *any* such activities for which you have no memory you should call your doctor immediately.

**Mental Alertness:** FLURAZEPAM may affect your ability to be alert. DO NOT DRIVE A CAR or operate potentially dangerous machinery until you experience how this drug will affect you.

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**Memory Problems:** All benzodiazepine sleeping pills can cause a special type of memory loss (amnesia); you may not recall events that occurred during some period of time, usually several hours, after taking the drug. This lapse is usually not a problem, because the person taking the sleeping pill intends to be asleep during this critical period of time. But it can be a problem if you take the medication to induce sleep while travelling, such as during an airplane flight, because you may wake up before the effect of the drug is gone. This has been called “traveller’s amnesia”. DO NOT TAKE FLURAZEPAM when a full night’s sleep is not possible before you would again need to be active and functional; e.g., an overnight flight of less than 8 hours. Memory lapses may occur in such situations. Your body needs time to eliminate the medication from your system.

**Tolerance/Withdrawal Symptoms:** After nightly use for more than a few weeks benzodiazepines may lose some of their effectiveness. You may also develop a degree of dependence. “Withdrawal” effects can occur when patients stop taking benzodiazepine sleeping pills. The effects may occur following use for only a week or two but may be more common and severe after long periods of continuous use. For example, you may experience an increase in sleep difficulties (rebound insomnia) and/or increased daytime anxiety (rebound anxiety) for one or two days after discontinuing FLURAZEPAM.

Other withdrawal symptoms following abrupt stopping of sleeping pills may range from unpleasant feelings to a major withdrawal syndrome that may include abdominal and muscle cramps, vomiting, sweating, tremor, and rarely, convulsions. The severe symptoms are uncommon.

**Dependence/Abuse:** All benzodiazepine sleeping pills can cause dependence (addiction) especially when used regularly for more than a few weeks, or at higher doses. Some people develop a need to continue taking these drugs, either at the prescribed dose or at higher doses not only for continued therapeutic effect, but also to avoid withdrawal symptoms or to achieve non-therapeutic effects.

Individuals who depend, or have depended at any time in the past, on alcohol or other drugs may be at particular risk of becoming dependent on drugs of this class. But ALL PEOPLE ARE AT SOME RISK. Consider this matter before you take these medications beyond a few weeks.

**Mental and Behavioural Changes:** A variety of abnormal thinking and behaviour changes may occur when you use benzodiazepine sleeping pills. Some of these changes include aggressiveness and extroversion which seem out of character. Other changes, although rare, can be more unusual and extreme such as confusion, strange behaviour, restlessness, illusions, hallucinations, feeling like you are not yourself, worsening insomnia and worsening depression, including suicidal thinking.

It is rarely clear whether such symptoms are caused by the medication, or by an illness that was present before the medication was used, or are simply spontaneous happenings. If you develop any unusual disturbing thoughts or behaviour while using FLURAZEPAM, discuss the matter immediately with your doctor.

### **Worsening of Side Effects**

DO NOT CONSUME ALCOHOL WHILE TAKING FLURAZEPAM. Some medicines may also worsen side effects that some patients experience with FLURAZEPAM (see “INTERACTIONS WITH THIS MEDICATION”).

**Elderly:** An increased risk of falls and fractures has been reported in elderly people who take benzodiazepines such as FLURAZEPAM.

**Effects on Pregnancy:** Certain benzodiazepine sleeping pills have been linked to birth defects when taken during the early months of pregnancy. In addition, benzodiazepine sleeping pills 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 FLURAZEPAM at any time during pregnancy.

### **BEFORE you use FLURAZEPAM talk to your doctor or pharmacist if:**

- You have a lung disease or breathing problems.
- You have liver or kidney condition.
- You have a history of depression and/or suicide thoughts or attempts.
- You have had unexpected reactions to alcohol or sedative medications in the past, such as irritability, aggression, hallucinations, etc.
- You have a history of drug or alcohol abuse or addiction.
- You are planning to become pregnant, you are pregnant, or you become pregnant while taking this medication.
- You are breastfeeding.
- You consume alcohol.
- You are taking other medicines, including drugs you can buy without a prescription.
- You have lactose intolerance.

### **INTERACTIONS WITH THIS MEDICATION**

FLURAZEPAM may produce more pronounced side effects when coadministered with alcohol, other tranquilizers or sleeping pills, sedative antihistamines, narcotic analgesics, anticonvulsants, antipsychotics and antidepressants or other psychotropic medications which themselves can make you sleepy.

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Compounds which inhibit certain hepatic enzymes (particularly cytochrome P450) may enhance the activity of benzodiazepines. Examples include cimetidine or erythromycin. Do not take FLURAZEPAM if you drink alcohol. DO NOT USE FLURAZEPAM along with other medications without first discussing this with your doctor.

### PROPER USE OF THIS MEDICATION

Benzodiazepine sleeping pills are effective medications and are relatively free of serious problems when used for the short-term management of insomnia. Insomnia may last only for a short time and may respond to brief treatment. The risks and benefits of prolonged use should be discussed with your doctor.

#### Usual dose:

FLURAZEPAM is a prescription medication intended to help you sleep. Follow your doctor's advice about how to take FLURAZEPAM, when to take it, and how long to take it.

Adults: The recommended dose is 30 mg just before bedtime, although some patients may require only 15 mg.

Elderly and/or Debilitated Patients should start with 15 mg just before bedtime.

DO NOT TAKE FLURAZEPAM if it is not prescribed for you.

DO NOT TAKE FLURAZEPAM for more than 7 to 10 days without first consulting your doctor. If you still have problems sleeping after you finish your capsules, contact your doctor again.

The lowest effective dose should be used.  
DO NOT INCREASE THE PRESCRIBED DOSE.

Do not take FLURAZEPAM if you drink alcohol.

Do not take FLURAZEPAM when a full night's sleep is not possible before you would again need to be active and functional.

Do not drive a car or operate potentially dangerous machinery until you experience how FLURAZEPAM will affect you the next day.

FLURAZEPAM is not for use in children under 18 years of age.

#### Overdose:

Manifestations of flurazepam hydrochloride overdosage include somnolence, confusion and coma.

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

#### Missed Dose:

If you forget to take FLURAZEPAM capsules, do not take a double dose to make up for the forgotten individual dose. Take the next dose at the usual time.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

#### Common Side Effects

Benzodiazepine sleeping pills may cause drowsiness, dizziness, light-headedness, and difficulty with coordination. Users must be cautious about engaging in hazardous activities requiring complete mental alertness, e.g., operating machinery or driving a motor vehicle.

DO NOT drink alcohol while using FLURAZEPAM. DO NOT USE benzodiazepine sleeping pills along with other medications without first discussing this with your doctor.

How sleepy you are the day after you use one of these sleeping pills depends on your individual response and on how quickly your body gets rid of the medication. The larger the dose, the more likely that you will experience drowsiness, etc., the next day. For this reason, it is important that you use the lowest dose possible that will still help you sleep at night. Benzodiazepines which are eliminated rapidly tend to cause less drowsiness the next day, but may cause withdrawal problems the day after use.

Elderly patients are especially susceptible to side effects. Excessive drowsiness in the elderly may result in falls and fractures.

Rare cases of severe allergic reactions have been reported. Symptoms may include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking FLURAZEPAM.

Withdrawal-related side effects: See "WARNINGS AND PRECAUTIONS, Tolerance/Withdrawal Symptoms".

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### 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 call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Unexpected reactions such as excitement, agitation, hyperactivity, hallucination, worsened insomnia, aggressiveness, irritability, rages, psychoses, and violent behaviour		*	
	Severe allergic Reactions (swelling of the tongue or throat, trouble breathing, nausea and vomiting)			*
	Depressed mood; thoughts of death or suicide		*	
Very rare	Somnambulism (sleepwalking) – getting out of bed while not fully awake and do activities you do not remember the day after		*	

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

### HOW TO STORE IT

Keep in a tightly closed, light-resistant container. Store at 15-30°C.

Keep out of 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](http://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  
Address Locator: 0701C  
Ottawa, ON 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](http://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 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](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca)

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