

Medication Guide
Flurazepam Hydrochloride Capsules, USP
(flur az' e pam hye'' droe klor' ide)



What is the most important information I should know about flurazepam hydrochloride capsules?

- **Flurazepam hydrochloride capsules are a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.** Get emergency help right away if any of the following happens:
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation).Do not drive or operate heavy machinery until you know how taking flurazepam hydrochloride capsules with opioids affect you.
- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including flurazepam hydrochloride capsules, which can lead to overdose and serious side effects including coma and death.
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including flurazepam hydrochloride capsules.** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - **You can develop an addiction even if you take flurazepam hydrochloride capsules exactly as prescribed by your healthcare provider.**
 - **Take flurazepam hydrochloride capsules exactly as your healthcare provider prescribed.**
 - Do not share your flurazepam hydrochloride capsules with other people.
 - Keep flurazepam hydrochloride capsules in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Flurazepam hydrochloride capsules can cause physical dependence and withdrawal reactions, especially if you continue to take flurazepam hydrochloride capsules for several days to several weeks.
 - **Do not suddenly stop taking flurazepam hydrochloride capsules.** Stopping flurazepam hydrochloride capsules suddenly can cause serious and life-threatening side effects, including unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.**
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.

- Do not take more flurazepam hydrochloride capsules than prescribed or take flurazepam hydrochloride capsules for longer than prescribed.
- After taking flurazepam hydrochloride capsules, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with flurazepam hydrochloride capsules. Reported activities include:
 - driving a car (“sleep-driving”)
 - making and eating food
 - talking on the phone
 - having sex
 - sleep-walking

Call your healthcare provider right away if you find out that you have done any of the above activities after taking flurazepam hydrochloride capsules.

What are flurazepam hydrochloride capsules?

- Flurazepam hydrochloride capsules are a prescription medicine used to treat certain types of insomnia including difficulty falling asleep, waking up often during the night, or waking up early in the morning.
- **Flurazepam hydrochloride is a federal controlled substance (C-IV) because it contains flurazepam that can be abused or lead to dependence.** Keep in a safe place to prevent misuse and abuse. Selling or giving away flurazepam hydrochloride capsules may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if flurazepam hydrochloride capsules are safe and effective in children.

Do not take flurazepam hydrochloride capsules if you:

- are allergic to flurazepam hydrochloride, other benzodiazepines, or any of the ingredients in flurazepam hydrochloride capsules. See the end of this Medication Guide for a complete list of ingredients in flurazepam hydrochloride capsules. Symptoms of a serious allergic reaction can include:
 - swelling of your face, lips, and throat that may cause difficulty breathing or swallowing
 - nausea and vomiting

Before you take flurazepam hydrochloride capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of depression, mental illness or, suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant.
 - Taking Flurazepam hydrochloride late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems).
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with Flurazepam hydrochloride.
 - There is a pregnancy registry for women who take Flurazepam hydrochloride during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. If you become pregnant during treatment with Flurazepam hydrochloride, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visiting <https://womensmentalhealth.org/pregnancyregistry/>.
- are breastfeeding, or plan to breastfeed.
 - Talk to your healthcare provider about the best way to feed your baby if you take flurazepam hydrochloride capsules.

- Breastfeeding is not recommended during treatment with Flurazepam hydrochloride.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking flurazepam hydrochloride capsules with certain other medicines can cause side effects or affect how well flurazepam hydrochloride capsules or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

Do not take flurazepam hydrochloride capsules with other medicines that can make you sleepy unless your healthcare provider tells you to.

How should I take flurazepam hydrochloride capsules?

- See **“What is the most important information I should know about flurazepam hydrochloride capsules?”**
- Take flurazepam hydrochloride capsules exactly as your healthcare provider tells you to take it.
- Take flurazepam hydrochloride capsules right before you get into bed.
- Do not take flurazepam hydrochloride capsules unless you are able to get a full night’s sleep before you must be active again.
- If you take too many flurazepam hydrochloride capsules, get emergency treatment right away.

What are the possible side effects of flurazepam hydrochloride capsules? Flurazepam hydrochloride capsules may cause serious side effects, including:

- See **“What is the most important information I should know about flurazepam hydrochloride capsules?”**
- **Other conditions.** Call your healthcare provider if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- **Severe allergic reactions.** Symptoms include swelling of the tongue or throat, and trouble breathing. Other symptoms may include nausea and vomiting. Get emergency medical help right away if you have these symptoms after taking flurazepam hydrochloride capsules.
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **Flurazepam hydrochloride capsules can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how flurazepam hydrochloride capsules affect you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking flurazepam hydrochloride capsules without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, flurazepam hydrochloride capsules may make your sleepiness or dizziness much worse.
- **Depression.** Pre-existing depression may emerge or worsen during use of benzodiazepines including flurazepam hydrochloride capsules.

The most common side effects of flurazepam hydrochloride capsules include:

- dizziness
- light-headedness
- loss of coordination
- drowsiness
- staggering
- falling

These are not all the possible side effects of flurazepam hydrochloride capsules. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800- FDA-1088.**

How should I store flurazepam hydrochloride capsules?

- Store at 20° to 25°C (68° to 77°F).
- Keep flurazepam hydrochloride capsules in a tightly closed container and out of the light.
- **Keep flurazepam hydrochloride capsules and all medicines out of the reach of children.**

General information about the safe and effective use of flurazepam hydrochloride capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use flurazepam hydrochloride capsules for a condition for which it was not prescribed. Do not give flurazepam hydrochloride capsules to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about flurazepam hydrochloride capsules that is written for healthcare professionals.

What are the ingredients in flurazepam hydrochloride capsules?

Active Ingredient: flurazepam hydrochloride

Inactive Ingredients: Anhydrous lactose, colloidal silicon dioxide, gelatin, FD&C Blue #1, FD&C Red #3, mannitol, magnesium stearate, talc, and titanium dioxide.

Additionally, capsule shells of 15 mg and 30 mg are imprinted with black pharmaceutical ink. The compositions of the black pharmaceutical ink are black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, and strong ammonia solution.

Manufactured for:

Chartwell RX, LLC.

Congers, NY 10920

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If you would like more information, call **Chartwell RX, LLC. at 1-845-232-1683.**

This Medication Guide has been approved by the U.S. Food and Drug Administration.