

MEDICATION GUIDE

Dalmane® (DAL-main) Capsules, 15 mg and 30 mg 
is a Sedative-Hypnotic indicated for Insomnia

Generic name: flurazepam (flew-raz-e-pam) hydrochloride capsules

R only

Read this Medication Guide carefully before you start taking your medicine and each time you get more, since there may be new information. It does not contain all the information about your medicine that you may need to know, so please ask your doctor, nurse or pharmacist if you have any questions.

IMPORTANT

YOUR DOCTOR HAS PRESCRIBED THIS DRUG FOR YOUR USE ONLY. DO NOT LET ANYONE ELSE USE IT. KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN AND PETS. If a child puts a Dalmane® capsule in his or her mouth or swallows it, call your local Poison Control Center or go immediately to the nearest emergency room.

What is the most important information I should know about sedative-hypnotic drugs?

After taking a sedative-hypnotic drug, 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 medications that make you sleepy with a sedative-hypnotic drug.
Reported activities include:

- driving a car ("sleep-driving")
- making and eating food
- talking on the phone
- having sex
- sleep-walking

Important:

1. Take a sedative-hypnotic drug exactly as prescribed:

- Do not take more sedative-hypnotic drugs than prescribed.
- Take the sedative-hypnotic drug right before you get in bed, not sooner.

2. Do not take a sedative-hypnotic drug if you:

- drink alcohol
- take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take a sedative-hypnotic drug with your other medicines
- cannot get a full night sleep

3. Call your doctor right away if you find out that you have done any of the above activities after taking a sedative-hypnotic drug.

What is Dalmane®?

Dalmane® is a sedative-hypnotic agent used to treat insomnia (difficulty falling asleep and staying asleep).

Who should not take Dalmane®?

Do not use Dalmane® if you are:

- allergic to anything in Dalmane®. (Being allergic may include having a rash, itching, swelling or breathing difficulties.) See the end of this Medication Guide for a complete list of ingredients in Dalmane®. In rare cases patient have had additional symptoms such as shortness of breath, throat closing, or nausea and vomiting that suggest an allergic reaction. Some patients have required medical therapy in the emergency department as these rare complications could be fatal. Patients who experience these symptoms should seek medical attention and discontinue taking the sedative-hypnotic drug.
- pregnant or intending to become pregnant. If a woman becomes pregnant while taking Dalmane®, she should discontinue use immediately.
- under 15 years of age. Dalmane® has not been studied in children.

How should I take Dalmane®?

Dalmane® comes as a capsule to take by mouth. You should take Dalmane®, or other sedative-hypnotic medications, **exactly** as directed by your doctor. It usually is taken right before you get in bed, not sooner. If you forget to take Dalmane® at bedtime, you are unable to fall asleep, and you will still be able to stay in bed for a full night's sleep, you may take Dalmane® at that time. Do not take a double dose of Dalmane® to make up for a missed dose.

The smallest possible effective dose is suggested for elderly patients due to the risk of the development of oversedation, dizziness, confusion and/or loss of coordination.

Sleep problems are often temporary, requiring treatment for a very short time. You should not use Dalmane[®], or any other sedative-hypnotic medications, for long periods of time without talking to your doctor about the risks and benefits of prolonged use.

In the case of a suspected overdose, you should contact your local poison control center immediately.

What should I avoid while taking Dalmane[®]?

Do not drink alcohol or take other medications that depress the central nervous system.

While taking Dalmane[®], do not engage in any hazardous occupations requiring complete mental alertness such as operating machinery or driving a car.

What are the possible or reasonably likely side effects of Dalmane[®]?

Dizziness, drowsiness, light-headedness, staggering, loss of coordination and falling have occurred, particularly in elderly or debilitated persons. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported are headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, nervousness, talking more than usual, anxiety, irritability, weakness, pounding heartbeat, chest pain, body and joint pains and difficulty urinating.

General information about the safe and effective use of Dalmane[®]

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns about taking this, or any sedative-hypnotic medication, please ask your doctor. For detailed information regarding Dalmane[®] please consult the physician's package insert. Do not use for conditions for which this medication was not prescribed. Do not give this medication to others.

What are the ingredients of Dalmane[®] Capsules?

Active Ingredient: flurazepam hydrochloride (15 mg or 30 mg)

Inactive Ingredients: Each 15 mg capsule also contains cornstarch, lactose, magnesium stearate and talc; gelatin capsule shells contain D&C Red No. 28, FD&C Red No. 40, FD&C Yellow No. 6 and D&C Yellow No. 10. Each 30 mg capsule also contains cornstarch, lactose and magnesium stearate; gelatin capsule shells contain FD&C Blue No. 1, FD&C Yellow No. 6, D&C Yellow No. 10 and either FD&C Red No. 3 or FD&C Red No. 40.

How should I store Dalmane® Capsules?

- Store Dalmane® Capsules at 25°C (77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [see USP Controlled Room Temperature].
- **KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN.** If a child accidentally takes Dalmane®, call your local Poison Control Center or go immediately to the nearest emergency room.

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

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