

## **LORAZEPAM Tablets**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

### **Information about LORAZEPAM**

LORAZEPAM is available as 1 mg and 2 mg tablets containing respectively 1 mg and 2 mg lorazepam.

Lorazepam is a benzodiazepine with anxiolytic and sedative effects. LORAZEPAM has a tranquilizing action on the central nervous system. Its actions are mediated by enhancement of the activity of GABA, a major inhibitory neurotransmitter in the brain.

LORAZEPAM is used in the following conditions:

- Short-term management of anxiety disorders, short-term relief of anxiety symptoms, or anxiety associated with depressive symptoms: generalized anxiety disorder, acute stress disorder, post-traumatic stress disorder, panic attacks, anxiety associated with severe or painful medical illness
- As a hypnotic in the short-term management of insomnia
- It is used for its sedative and amnesic properties in premedication for procedures such as dental treatment and endoscopy and as an adjunct in regimens for the control of nausea and vomiting associated with cancer chemotherapy
- Management of symptoms of alcohol withdrawal
- Prevention and treatment of delirium tremens

### **The way to take LORAZEPAM**

Take LORAZEPAM as prescribed by your physician.

The dose, frequency of administration, and duration of therapy must be adjusted individually on the basis of the condition under treatment and the patient's response.

- The usual dose of lorazepam for the treatment of anxiety disorders is 1 to 6 mg daily (one tablet of LORAZEPAM 1 mg or half a tablet of LORAZEPAM 2 mg to 3 tablets of LORAZEPAM 2 mg daily) in 2 or 3 divided doses with the largest dose taken at night, up to 10 mg/day.
  - The usual dose used for panic attacks is 3 to 5 mg daily
  - A single oral dose of 1 to 4 mg at bedtime may be given for insomnia associated with anxiety or transient situational stress.
  - For premedication, adults may be given a dose of 2 to 3 mg by mouth the night before the operation followed if necessary the next morning by a smaller dose. Alternatively, 2 to 4 mg may be given 1 to 2 hours before an operation.
  - In patients receiving modestly emetogenic chemotherapy, lorazepam 1 to 2 mg by mouth may be added to antiemetic therapy for the prophylaxis of nausea and vomiting
- Lorazepam should be given in reduced dosage to elderly or debilitated patients. An initial dose of 1 to 2 mg/day in divided doses is recommended to be adjusted as needed and tolerated.

The dosage of lorazepam should be increased gradually when needed.

### **Duration of treatment**

Do not take more of this medicine, take it longer than prescribed by your doctor, or discontinue the treatment without consulting your doctor.

The treatment must be as brief as possible. The indication must be regularly reevaluated, especially in the absence of symptoms. The global duration of treatment must not exceed 8 to 12 weeks for the majority of patients including the period of reduction of the dosage.

In some cases, it may be necessary to prolong the treatment but with periodic evaluation of the patient's state.

**In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

The specific antagonist of benzodiazepines is flumazenil.

**In case of missed dose**

If you take several doses per day and you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**Contraindications**

This drug is contraindicated in case of:

- Hypersensitivity to benzodiazepines
- Severe respiratory failure
- Syndrome of sleep apnea
- Severe hepatic impairment
- Acute narrow angle glaucoma

**Precautions**

- This drug is not recommended for use in patients with primary depressive disorder or psychosis.
- Caution should be exercised when driving a car or operating dangerous machinery since drowsiness may occur.
- This medicine can be habit-forming. A prolonged use and high doses may lead to physical and psychological dependence.
- Do not discontinue the treatment without consulting your doctor; he may want you to discontinue the drug progressively rather than abruptly. The treatment must be progressively stopped, in case of prolonged use and/or high doses. Abrupt discontinuation of the treatment may lead to withdrawal symptoms.
- This drug must be used with caution in elderly or debilitated patients, persons with renal or hepatic insufficiency, in case of respiratory failure and in addiction-prone patients.
- As with other benzodiazepines, periodic blood counts and liver function tests are recommended for patients on long-term therapy.
- Benzodiazepines may aggravate the symptoms of myasthenia.
- Consult your doctor before using this medication in case of pregnancy. This drug should not be used in the first trimester of pregnancy unless absolute necessity and high doses should be avoided during the third trimester.
- This drug should not be used during lactation.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Special precautions should be taken with drugs that cause drowsiness or relaxation.

The concomitant use of this drug with alcoholic beverages or barbiturates is not recommended.

Use with cautions with other centrally active drugs such as antipsychotics, tranquilizers, sedative antidepressants, hypnotics, narcotic analgesics and cough suppressants, sedative H1 antagonists, baclofen, clozapine.

**Adverse reactions**

This drug is generally tolerated at therapeutic doses. Adverse reactions, if they occur, are usually observed at the beginning of therapy and generally disappear on continued medication or upon decreasing the dose.

The most reported adverse reactions include sedation, dizziness, weakness, unsteadiness.

Less frequent adverse reactions are disorientation, depression, nausea, change in appetite, headache, sleep disturbance, agitation, and dermatological symptoms

Inform your doctor if any adverse reaction appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

LORAZEPAM 1 mg, pack of 40 tablets  
LORAZEPAM 2 mg, pack of 40 tablets

**Revision date: 05/2006**

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