#### BENZODIAZEPINES

Some commonly used brand names are:

Ativan (lorazepam), Dalmane (flurazepam), Diastat or Valium (diazepam), , Doral (quazepam), Halcion (triazolam), Klonopin (clonazepam), Librium (chlordiazepoxide), Paxipam (halazepam), ProSom (estazolam), Restoril (temazepam), Serax (oxazepam), Tranxene-SD (clorazepate), , Xanax (alprazolam)

# **Description**

Benzodiazepines (ben-zoe-dye-AZ-e-peens) belong to the group of medicines called central nervous system (CNS) depressants (medicines that slow down the nervous system).

Some benzodiazepines are used to relieve anxiety. However, benzodiazepines should not be used to relieve nervousness or tension caused by the stress of everyday life.

Some benzodiazepines are used to treat insomnia (trouble in sleeping). However, if used regularly (for example, every day) for insomnia, they usually are not effective for more than a few weeks.

Many of the benzodiazepines are used in the treatment of other conditions, also. Diazepam is used to help relax muscles or relieve muscle spasm. Diazepam injection is used before some medical procedures to relieve anxiety and to reduce memory of the procedure. Chlordiazepoxide, clorazepate, diazepam, and oxazepam are used to treat the symptoms of alcohol withdrawal. Alprazolam and clonazepam are used in the treatment of panic disorder. Clonazepam, clorazepate, diazepam, and lorazepam are used in the treatment of certain convulsive (seizure) disorders, such as epilepsy. The benzodiazepines may also be used for other conditions as determined by your doctor.

Benzodiazepines may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses.

### **Before Using This Medicine**

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For benzodiazepines, the following should be considered:

**Allergies:** Tell your doctor if you have ever had any unusual or allergic reaction to benzodiazepines. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes. Certain benzodiazepine products may contain lactose, parabens, or soybean oil.

**Pregnancy:** Chlordiazepoxide and diazepam have been reported to increase the chance of birth defects when used during the first 3 months of pregnancy. Although similar problems have not

been reported with the other benzodiazepines, the chance always exists since all of the benzodiazepines are related.

Studies in animals have shown that clonazepam, lorazepam, and temazepam cause birth defects or other problems, including death of the animal fetus.

Too much use of a benzodiazepine during pregnancy may cause the baby to become dependent on the medicine. This may lead to withdrawal side effects after birth. Also, use of benzodiazepines during pregnancy, especially during the last weeks, may cause body temperature problems, breathing problems, difficulty in feeding, drowsiness, or muscle weakness in the newborn infant.

**Older adults:** Most of the side effects of these medicines are more likely to occur in the elderly, who are usually more sensitive to the effects of benzodiazepines.

Taking benzodiazepines for trouble in sleeping may cause more daytime drowsiness in elderly patients than in younger adults. In addition, falls and related injuries are more likely to occur in elderly patients taking benzodiazepines.

**Other medicines:** When you are taking benzodiazepines it is especially important that your health care professional know if you are taking any of the following:

- Central nervous system (CNS) depressants (medicines that cause drowsiness) The CNS depressant effects of either these medicines or benzodiazepines may be increased; your doctor may want to change the dose of either or both medicines
- Fluvoxamine (e.g., Luvox)
- Itraconazole (e.g., Sporanox)
- Ketoconazole (e.g., Nizoral)
- Nefazodone (e.g., Serzone)Higher blood levels of benzodiazepines may occur, increasing the chance that side effects will occur; your doctor may want to change the dose of either or both medicines, or give you a different medicine

Other medical problems: The presence of other medical problems may affect the use of benzodiazepines. Make sure you tell your doctor if you have any other medical problems, especially:

- Alcohol abuse (or history of)
- Drug abuse or dependence (or history of) Dependence on benzodiazepines may be more likely to develop
- Brain disease CNS depression and other side effects of benzodiazepines may be more likely to occur
- Difficulty in swallowing (in children)

- Emphysema, asthma, bronchitis, or other chronic lung disease
- Glaucoma
- Hyperactivity
- Mental illness (severe)
- Myasthenia gravis
- Porphyria
- Sleep apnea (temporary stopping of breathing during sleep) Benzodiazepines may make these conditions worse
- Epilepsy or history of seizures Although some benzodiazepines are used in treating epilepsy, starting or suddenly stopping treatment with these medicines may increase the risk of seizures
- Kidney or liver disease Higher blood levels of benzodiazepines may result, increasing the chance that side effects will occur

### **Proper Use**

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. If too much is taken, it may become habit-forming (causing mental or physical dependence).

If you think this medicine is not working properly after you have taken it for a few weeks, do not increase the dose. Instead, check with your doctor.

For patients taking this medicine on a regular schedule for epilepsy or other seizure disorder:

In order for this medicine to control your seizures, it must be taken every day in regularly spaced doses as ordered by your doctor. This is necessary to keep a constant amount of the medicine in the blood. To help keep the amount constant, do not miss any doses.

For patients taking this medicine for insomnia:

Do not take this medicine when your schedule does not permit you to get a full night's sleep (7 to 8 hours). If you must wake up before this, you may continue to feel drowsy and may experience confusion or memory problems, because the effects of the medicine have not had time to wear off.

**Dosing:** The dose of benzodiazepines will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of benzodiazepines. If your dose is different, do not change it unless your doctor tells you to do so.

- For clonazepam
  - o For control of seizures:
    - Adults At first, 0.5 milligram (mg) three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 20 mg a day.

- Infants and children younger than 10 years of age Dose is based on body weight and must be determined by your doctor.
- o For panic disorder:
  - Adults At first, 0.25 mg two times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 4 mg a day.
  - Children Use and dose must be determined by your doctor.

# For diazepam

- o For anxiety:
  - Adults 2 to 10 mg, two to four times a day.
  - Children 6 months of age and older Dose is based on body weight or size and must be determined by your doctor.
  - Children younger than 6 months of age Use is not recommended.
  - Older adults 2 to 2.5 mg, one or two times a day. Your doctor may increase your dose if needed.
- o For sedation during withdrawal from alcohol:
  - Adults At first, 10 mg, three or four times a day. Your doctor will set up a schedule that will gradually decrease your dose.
  - Children Use and dose must be determined by your doctor.
- For control of seizures:
  - Adults 2 to 10 mg, two to four times a day.
  - Children 6 months of age and older Dose is based on body weight or size and must be determined by your doctor.
  - Children younger than 6 months of age: Use is not recommended.
  - Older adults: 2 to 2.5 mg, one or two times a day. Your doctor may increase your dose if needed.
- o For relaxing muscles:
  - Adults: 2 to 10 mg, three or four times a day.
  - Children 6 months of age and older: Dose is based on body weight or size and must be determined by your doctor.
  - Children younger than 6 months of age: Use is not recommended.
  - Older adults: 2 to 2.5 mg, one or two times a day. Your doctor may increase your dose if needed.

### For lorazepam

- o For anxiety:
  - Adults and teenagers: 1 to 3 milligrams (mg), two or three times a day.
  - Children younger than 12 years of age: Use and dose must be determined by your doctor.
  - Older adults: 0.5 to 2 mg a day, taken in smaller doses during the day.
- For trouble in sleeping:
  - Adults and teenagers: 2 to 4 mg taken at bedtime.
  - Children younger than 12 years of age: Use and dose must be determined by your doctor.
- o For injection dosage form:
- o For sedation before surgery or other procedures:

- Adults: Dose is based on body weight and will be determined by your doctor. However, the dose usually is not more than 4 mg, injected into a
- muscle or vein.
- Children younger than 18 years of age: Use and dose must be determined by your doctor.
- o For control of seizures:
  - Adults: At first, 4 mg slowly injected into a vein. The dose may be repeated after ten to fifteen minutes if needed.
  - Children younger than 18 years of age: Use and dose must be determined by your doctor.

## For oxazepam

- o For anxiety:
  - Adults: 10 to 30 milligrams (mg), three or four times a day.
  - Children younger than 12 years of age: Use and dose must be determined by your doctor.
  - Older adults: At first, 5 mg, one or two times a day or 10 mg, three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 15 mg, four times a day.
- o For sedation during withdrawal from alcohol:
  - Adults: 15 to 30 mg, three or four times a day.
  - Children younger than 12 years of age: Use and dose must be determined by your doctor.

### ■ For temazepam

- o For trouble in sleeping:
  - Adults: 15 milligrams (mg) at bedtime. Your doctor may change your dose if needed.
  - Children younger than 18 years of age: Use and dose must be determined by your doctor.
  - Older adults: At first, 7.5 mg at bedtime. Your doctor may increase your dose if needed.

# Missed dose:

If you are taking this medicine regularly (for example, every day as for epilepsy) and you miss a dose, take it right away if you remember within an hour or so of the missed dose. However, if you do not remember until later, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

#### **Precautions**

If you will be taking a benzodiazepine regularly for a long time:

Your doctor should check your progress at regular visits to make sure that this medicine does not cause unwanted effects. If you are taking a benzodiazepine for convulsions (seizures), this is also important during the first few months of treatment. Check with your doctor at regular visits to see if you need to continue taking this medicine.

If you are taking a benzodiazepine for epilepsy or another seizure disorder:

■ Your doctor may want you to carry a medical identification card or bracelet stating that you are taking this medicine.

If you are taking a benzodiazepine for insomnia (trouble in sleeping):

- If you think you need this medicine for more than 7 to 10 days, be sure to discuss it with your doctor. Insomnia that lasts longer than this may be a sign of another medical problem.
- You may have difficulty sleeping (rebound insomnia) for the first few nights after you stop taking this medicine.

Benzodiazepines may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses. Some signs of dependence on benzodiazepines are:

- A strong desire or need to continue taking the medicine.
- A need to increase the dose to receive the effects of the medicine.
- Withdrawal effects (for example, irritability, nervousness, trouble in sleeping, abdominal or stomach cramps, trembling or shaking) occurring after the medicine is stopped.

If you think you may have become mentally or physically dependent on this medicine, check with your doctor. Do not stop taking it suddenly.

If you have been taking this medicine in large doses or for a long time, do not stop taking it without first checking with your doctor. Your doctor may want you to reduce gradually the amount you are taking before stopping completely. Stopping this medicine suddenly may cause withdrawal side effects, including seizures. Stopping this medicine suddenly is most likely to cause seizures if you have been taking it for epilepsy or another seizure disorder.

This medicine will add to the effects of alcohol and other central nervous system (CNS) depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates; medicine for seizures; muscle relaxants; or anesthetics, including some dental anesthetics. This effect may last for a few days after you stop taking this medicine. Check with your doctor before taking any of the above while you are taking benzodiazepines.

If you think you or someone else may have taken an overdose of this medicine, get emergency help at once . Taking an overdose of a benzodiazepine or taking alcohol or other CNS depressants with the benzodiazepine may lead to unconsciousness and possibly death. Some signs of an overdose are continuing slurred speech or confusion, severe drowsiness, severe weakness, and staggering.

If you develop any unusual and strange thoughts or behavior while you are taking this medicine, be sure to discuss it with your doctor. Some changes that have occurred in people taking this medicine are like those seen in people who drink alcohol and then act in a manner that is not normal. Other changes may be more unusual and extreme, such as confusion, agitation, and hallucinations (seeing, hearing, or feeling things that are not there).

This medicine may cause some people, especially older persons, to become drowsy, dizzy, lightheaded, clumsy or unsteady, or less alert than they are normally. Even if taken at bedtime, it may cause some people to feel drowsy or less alert on arising. Make sure you know how you react to this medicine before you drive,

use machines, or do anything else that could be dangerous if you are dizzy or are not alert.

#### **Side Effects**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

#### ■ Less common

 Anxiety; confusion (may be more common in the elderly); fast, pounding, or irregular heartbeat; lack of memory of events taking place after benzodiazepine is taken (may be more common with triazolam); mental depression

#### Rare

Abnormal thinking, including disorientation, delusions (holding false beliefs that cannot be changed by facts), or loss of sense of reality; agitation; behavior changes, including aggressive behavior, bizarre behavior, decreased inhibition, or outbursts of anger; convulsions (seizures); hallucinations (seeing, hearing, or feeling things that are not there); hypotension (low blood pressure); muscle weakness; skin rash or itching; sore throat, fever, and chills; trouble in sleeping; ulcers or sores in mouth or throat (continuing); uncontrolled movements of body, including the eyes; unusual bleeding or bruising; unusual excitement, nervousness, or irritability; unusual tiredness or weakness (severe); yellow eyes or skin

# Symptoms of overdose

■ Confusion (continuing); convulsions (seizures); drowsiness (severe) or coma; shakiness; slow heartbeat; slow reflexes; slurred speech (continuing); staggering; troubled breathing; weakness (severe)

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

### ■ More common

 Clumsiness or unsteadiness; dizziness or lightheadedness; drowsiness; slurred speech

### ■ Less common or rare

Abdominal or stomach cramps or pain; blurred vision or other changes in vision; changes in sexual desire or ability; constipation; diarrhea; dryness of mouth or increased thirst; false sense of well-being; headache; increased bronchial secretions or watering of mouth; muscle spasm; nausea or vomiting; problems with urination; trembling or shaking; unusual tiredness or weakness

After you stop using this medicine, your body may need time to adjust. During this time, check with your doctor if you notice any of the following side effects:

#### ■ More common

o Irritability; nervousness; trouble in sleeping

#### ■ Less common

 Abdominal or stomach cramps; confusion; fast or pounding heartbeat; increased sense of hearing; increased sensitivity to touch and pain; increased sweating; loss of sense of reality; mental depression; muscle cramps; nausea or vomiting; sensitivity of eyes to light; tingling, burning, or prickly sensations; trembling or shaking

#### Rare

 Confusion as to time, place, or person; convulsions (seizures); feelings of suspicion or distrust; hallucinations (seeing, hearing, or feeling things that are not there)

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.