



Diazepam

Injection, USP

10 mg per 2 mL Simplist® ready-to-administer prefilled syringes available from Fresenius Kabi

Manufacturer prepared

24-month shelf life

Ready-to-administer

Clear and distinct labeling

Diazepam Injection, USP IMPORTANT SAFETY INFORMATION

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

- Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.
- Reserve concomitant prescribing of these drugs in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.
- The use of benzodiazepines, including diazepam, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing diazepam and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
- The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although diazepam is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of diazepam may precipitate acute withdrawal reactions, which can be life threatening. For patients using diazepam more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue diazepam.

CONTRAINDICATIONS

Diazepam injection is contraindicated in patients with a known hypersensitivity to this drug; acute narrow angle

glaucoma; and open angle glaucoma unless patients are receiving appropriate therapy.

WARNINGS AND PRECAUTIONS

Risks from Concomitant Use with Opioids: Concomitant use of benzodiazepines, including diazepam, and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of benzodiazepines and opioids in patients for whom alternative treatment options are inadequate.

Abuse, Misuse, and Addiction: The use of benzodiazepines, including diazepam, exposes users to the risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing diazepam and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.

Dependence and Withdrawal Reactions After Use of Diazepam More Frequently Than Recommended: To reduce risk of withdrawal reactions, use a gradual taper to discontinue diazepam. **Acute Withdrawal Reactions:** The continued use of benzodiazepines may lead to clinically significant physical dependence. If used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of diazepam or administration of flumazenil (a benzodiazepine antagonist) may precipitate acute withdrawal reactions, which can be life-threatening (e.g., seizures). **Protracted Withdrawal Syndrome:** In some cases, benzodiazepine users have developed a protracted withdrawal syndrome with withdrawal symptoms lasting weeks to more than 12 months.

Diazepam injection should not be administered to patients in shock, coma, or in acute alcoholic intoxication with depression of vital signs. Patients receiving diazepam should be cautioned against engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle.

Tonic status epilepticus has been precipitated in patients treated with intravenous diazepam for petit mal status or petit mal variant status.

Usage in Pregnancy: Avoid use during the first trimester of pregnancy. Until additional information is available, Diazepam Injection is not recommended for obstetrical use.

Pediatric Use: Efficacy and safety of parenteral diazepam has not been established in the neonate (30 days or less of

age). Prolonged central nervous system depression has been observed in neonates. In pediatric use for the treatment of status epilepticus, in order to obtain maximal clinical effect with the minimum amount of drug and thus to reduce the risk of hazardous side effects, such as apnea or prolonged periods of somnolence, it is recommended that the drug be given as a slow IV push over 1 minute.

Benzyl alcohol has been reported to be associated with a fatal gasping syndrome in premature infants.

Compromised kidney function: Metabolites of diazepam are excreted by the kidney; to avoid their excess accumulation, caution should be exercised in the administration to patients with compromised kidney function.

Propylene glycol toxicity has been reported in patients treated with diazepam injection at doses significantly greater than recommended. Propylene glycol toxicity is associated with an anion gap metabolic acidosis, serum hyperosmolality, and increased lactate.

Drug Interactions: If diazepam is to be combined with other psychotropic agents or anticonvulsant drugs, careful consideration should be given to the pharmacology of the agents to be employed, particularly with known compounds which may potentiate the action of diazepam, such as phenothiazines, narcotics, barbiturates, MAO inhibitors, and other antidepressants. In highly anxious patients with evidence of accompanying depression, particularly those who may have suicidal tendencies, protective measures may be necessary.

ADVERSE REACTIONS

Most commonly reported side effects were drowsiness, fatigue, and ataxia, venous thrombosis and phlebitis at the site of injection.

Adverse Event Contact Information: To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Manifestations of diazepam overdosage include somnolence, confusion, coma, and diminished reflexes. Respiration, pulse, and blood pressure should be monitored. General supportive measures should be employed, along with intravenous

fluids, and an adequate airway maintained. Dialysis is of a limited value.

INDICATIONS AND USAGE

- Diazepam is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.
- In acute alcohol withdrawal, diazepam may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.
- As an adjunct prior to endoscopic procedures if apprehension, anxiety or acute stress reactions are present, and to diminish the patient's recall of the procedures.
- Diazepam is a useful adjunct for the relief of skeletal muscle spasm due to reflex spasm to local pathology (such as inflammation of the muscles or joints, or secondary to trauma); spasticity caused by upper motor neuron disorders (such as cerebral palsy and paraplegia); athetosis; stiff-man syndrome; and tetanus.
- Diazepam Injection is a useful adjunct in status epilepticus.
- Diazepam is a useful premedication (the intramuscular route is preferred) for relief of anxiety and tension and to diminish the patient's recall of the procedure.

This Important Safety Information does not include all the information needed to use Diazepam Injection, USP safely and effectively. Please see full prescribing information, including BOXED WARNING, for Diazepam Injection, USP at www.simplist-us.com.

Diazepam

Injection, USP



Strength 10 mg per 2 mL

Concentration 5 mg per mL

Fill volume 2 mL

Unit of sale NDC 76045-204-20

Unit of sale bar code



(01)30376045204200

Pack size 24 per Carton

Blister dimensions 5.748" x 1.063"

Carton dimensions 6.25" x 2.402" x 6.575"

Wholesale numbers

Cardinal 5842893

Cencora 10279568

McKesson 2811768

Morris & Dickson 275859

**To place an order, contact your Sales Representative or call Customer Service at
1.888.386.1300 | www.simplist-us.com**