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Press Release

Hikma launches Diazepam Injection, USP in the US

London, UK, 8 July 2026 – Hikma Pharmaceuticals PLC (Hikma, Group), a multinational pharmaceutical company, today announced the launch of Diazepam Injection, USP, C-IV, 5 mg/mL (10 mg/2 mL), in 2 mL multi-dose vials, supplied in packs of 25, in the US.

“We are pleased to expand our injectable portfolio with the launch of Diazepam Injection, USP 10mg/2 mL multi-dose vial in the US following the launch of Diazepam Injection USP 50 mg/mL multidose vial in 2023,” said Jon Kafer, Vice President of Commercial for US Injectables. “This addition reflects our commitment to providing clinicians and patients with a comprehensive range of dosage options, ensuring reliable and convenient access to high-quality, affordable medicines across a range of care settings.”

Diazepam Injection, USP is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety; as an adjunct in the symptomatic relief of acute agitation, tremor, and delirium tremens in acute alcohol withdrawal; as an adjunct prior to endoscopic procedures if apprehension, anxiety or acute stress reactions are present; as an adjunct for the relief of skeletal muscle spasm; as a useful adjunct in status epilepticus; and as a premedication for relief of anxiety and tension in patients undergoing surgical procedures or cardioversion. Please see the full package insert for boxed warning and other important safety information.

According to IQVIA, the total US market for Diazepam Injection was approximately $77 million and 4.1 million units for the full year 2025.

- ENDS –

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

About Hikma

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB/stable S&P and BBB/stable Fitch)

Enquiries

Hikma Pharmaceuticals PLC
Susan Ringdal — +44 (0)20 7399 2760/ +44 7776 477050
EVP, Strategic Planning and Global Affairs

Steven Weiss — +1 732 788 8279
US Communications

Important Safety Information for Diazepam Injection, USP, C-IV

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 (see WARNINGS).**
- **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 (see WARNINGS and PRECAUTIONS).**
- **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 (see WARNINGS).**
- **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 (see INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION), 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 (see WARNINGS).**

CONTRAINDICATIONS

Diazepam 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 & PRECAUTIONS

- Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone.
- Do not exceed the recommended dosing frequency; avoid or minimize concomitant use of CNS depressants and other substances associated with abuse, misuse, and addiction (e.g., opioid analgesics, stimulants); and advise patients on the proper disposal of unused drug. If a substance use disorder is suspected, evaluate the patient and institute (or refer them for) early treatment, as appropriate.
- In some cases, benzodiazepine users have developed a protracted withdrawal syndrome with withdrawal symptoms lasting weeks to more than 12 months.
- Extreme care must be used in administering diazepam injection, particularly by the intravenous route, to the elderly, to very ill patients and to those with limited pulmonary reserve because of the possibility that apnea and/or cardiac arrest may occur. Concomitant use of barbiturates, alcohol or other central nervous system depressants increases depression with increased risk of apnea. Resuscitative equipment including that necessary to support respiration should be readily available.
- When diazepam is used with a narcotic analgesic, the dosage of the narcotic should be reduced by at least one-third and administered in small increments. In some cases the use of a narcotic may not be necessary.
- Diazepam injection should not be administered to patients in shock, coma, or in acute alcoholic intoxication with depression of vital signs. As is true of most CNS-acting drugs, 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.
- Although seizures may be brought under control promptly, a significant proportion of patients experience a return to seizure activity, presumably due to the short-lived effect of diazepam after intravenous administration. The physician should be prepared to re-administer the drug. However, diazepam is not recommended for maintenance, and once seizures are brought under control, consideration should be given to the administration of agents useful in longer term control of seizures.
- The usual precautions in treating patients with impaired hepatic function should be observed. 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.
- Since an increase in cough reflex and laryngospasm may occur with peroral endoscopic procedures, the use of

a topical anesthetic agent and the availability of necessary countermeasures are recommended.
- Propylene glycol toxicity has been reported in patients treated with diazepam injection at doses significantly greater than recommended. In these cases, diazepam was being used to treat alcohol withdrawal symptoms at doses greater than 900 mg/day.
- Until additional information is available, diazepam injection is not recommended for obstetrical use.
- Lower doses (usually 2 mg to 5 mg) should be used for elderly and debilitated patients due to increased risk of apnea and cardiovascular depression.

ADVERSE REACTIONS

Side effects most commonly reported were drowsiness, fatigue and ataxia; venous thrombosis and phlebitis at the site of injection. Other adverse reactions less frequently reported include:

CNS: confusion, depression [including respiratory depression], dysarthria, headache, hypoactivity, slurred speech, syncope, tremor, vertigo.
G.I.: constipation, nausea.
G.U.: incontinence, changes in libido, urinary retention.
Cardiovascular: bradycardia, cardiovascular collapse, hypotension.
EENT: blurred vision, diplopia, nystagmus.
Skin: urticaria, skin rash.
Other: hiccups, changes in salivation, neutropenia, jaundice. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances and stimulation have been reported; should these occur, use of the drug should be discontinued. Minor changes in EEG patterns, usually low-voltage fast activity, have been observed in patients during and after diazepam therapy and are of no known significance.

In peroral endoscopic procedures, coughing, depressed respiration, dyspnea, hyperventilation, laryngospasm and pain in throat or chest have been reported.

Because of isolated reports of neutropenia and jaundice, periodic blood counts and liver function tests are advisable during long-term therapy.

DRUG INTERACTIONS

The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. Benzodiazepines interact at $GABA_A$ sites and opioids interact primarily at mμ receptors. When benzodiazepines and opioids are combined, the potential for benzodiazepines to significantly worsen opioid-related respiratory depression exists. Limit dosage and duration of concomitant use of benzodiazepines and opioids, and monitor patients closely for respiratory depression and sedation.

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.

Diazepam injection has produced hypotension or muscular weakness in some patients particularly when used with narcotics, barbiturates or alcohol.

The clearance of diazepam and certain other benzodiazepines can be delayed in association with cimetidine administration. The clinical significance of this is unclear.

USE IN SPECIFIC POPULATIONS

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, apparently due to inability to biotransform diazepam into inactive metabolites. Benzyl alcohol has been reported to be associated with a fatal gasping syndrome in premature infants.

Pregnancy
Advise pregnant females that use of diazepam late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Benzodiazepines cross the placenta and may produce respiratory depression, hypotonia, and sedation.

Monitor neonates exposed to Diazepam injection during pregnancy or labor for signs of sedation, respiratory depression, hypotonia, and feeding problems. Monitor neonates exposed to Diazepam injection during pregnancy for signs of withdrawal; manage these neonates accordingly.

Instruct patients to inform their healthcare provider if they are pregnant. Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to diazepam during pregnancy.

Nursing
Advise patients that breastfeeding is not recommended during treatment with diazepam. Diazepam is present in breastmilk. There are reports of sedation, poor feeding and poor weight gain in infants exposed to benzodiazepines through breast milk. However, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Diazepam injection and any potential adverse effects on the breastfed infant from Diazepam injection or from the underlying maternal condition.

OVERDOSAGE

Overdosage is characterized by CNS depression ranging from drowsiness to coma. Manage with general supportive measures including intravenous fluids and airway maintenance. Flumazenil may be used adjunctively to, not a substitute for, supportive management of benzodiazepine overdose. Flumazenil can lead to withdrawal and adverse reactions, including seizures, particularly in the context of mixed overdosage with drugs that increase seizure risk (e.g., tricyclic and tetracyclic antidepressants) and in patients with long term benzodiazepine use and physical dependency. The risk of withdrawal seizures with flumazenil use may be increased in patients with epilepsy. Flumazenil is contraindicated in patients given benzodiazepines for control of a potentially life-threatening condition (e.g., status epilepticus). See the flumazenil injection Prescribing Information.

Consider contacting a poison center (1-800-222-1222), poisoncontrol.org or a medical toxicologist for additional overdosage management recommendations.

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 in patients who are to undergo surgical procedures. Intravenously, prior to cardioversion for the relief of anxiety and tension and to diminish the patient's recall of the procedure**.**

ENDING INFORMATION

For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured by:
Hikma Pharmaceuticals USA Inc.
Berkeley Heights, NJ 07922 USA