Press Release

Hikma launches Morphine Sulfate Injection, USP, in a prefilled syringe in the US

London, 14 July 2025 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Morphine Sulfate Injection, USP, in 2mg/mL and 4mg/mL doses in the US. The product has been launched in a prefilled syringe form and is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

According to IQVIA, US sales of Morphine Sulfate Injection, USP, 2mg/mL and 4mg/mL, were approximately $75 million in the 12 months ending May 2025.

Hikma is a top three supplier of generic injectable medicines by volume in the US[1], with a growing portfolio of more than 170 products. We are continuously expanding our portfolio of essential medicines and introducing new dosage forms that enhance patient care.

- 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.

Enquiries

Hikma Pharmaceuticals PLC

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

Steven Weiss
US Communications
+1 732 788 8279

About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB/stable S&P and BBB/stable Fitch)

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 9,500 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

[1] Source: IQVIA MAT May 2025, generic injectable volumes by eaches, excluding branded generics and Becton Dickinson

hikma.

Important Safety Information for Morphine Sulfate Injection, USP, in 2mg/mL and 4mg/mL:

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF MORPHINE SULFATE INJECTION

Addiction, Abuse, and Misuse
Because the use of Morphine Sulfate Injection exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of Morphine Sulfate Injection, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of Morphine Sulfate Injection are essential.

Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of Morphine Sulfate Injection and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome (NOWS)
If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

CONTRAINDICATIONS

Morphine Sulfate Injection is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity to morphine (e.g., anaphylaxis)

WARNINGS & PRECAUTIONS

- **Cardiovascular Instability –** High doses of intravenously administered morphine are excitatory, resulting from sympathetic hyperactivity and increase in circulatory catecholamines.
- **Opioid-Induced Hyperalgesia and Allodynia –** Cases of Opioid-Induced Hyperalgesia (OIH) have been reported, both with short-term and longer-term use of opioid analgesics.
- **Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients –**
    - Patients with Chronic Pulmonary Disease: Morphine Sulfate Injection-treated patients with significant chronic obstructive pulmonary disease or cor pulmonale, and those with a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive including apnea, even at recommended dosages of Morphine Sulfate Injection.
    - Elderly, Cachectic, or Debilitated Patients: Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients.
- **Interaction with Monoamine Oxidase Inhibitors –** Monoamine oxidase inhibitors (MAOIs) may potentiate the effects of morphine, including respiratory depression, coma, and confusion.
- **Adrenal Insufficiency –** Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use.
- **Severe Hypotension –** Morphine Sulfate Injection may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs.
- **Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness –** In patients who may be susceptible to the intracranial effects of CO_2 retention, Morphine

Sulfate Injection may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use in patients with impaired consciousness or coma.

- **Risks of Use in Patients with Gastrointestinal Conditions –** Morphine Sulfate Injection may cause spasm of the sphincter of Oddi. Opioids may cause increases in serum amylase.
- **Increased Risk of Seizures in Patients with Seizure Disorders –** Morphine Sulfate Injection may increase the frequency of seizures in patients with seizure disorders and may increase the risk of seizures occurring in other clinical settings associated with seizures.
- **Withdrawal –** Avoid the use of mixed agonist/antagonist or partial agonist analgesics in patients who are receiving Morphine Sulfate Injection. In these patients, mixed agonist/antagonist and partial agonist analgesics may reduce the analgesic effect and/or precipitate withdrawal symptoms.
- **Risks of Driving and Operating Machinery –** Morphine Sulfate may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving or operating machinery.

ADVERSE REACTIONS

Serious adverse reactions include respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest. Rarely, anaphylactoid reactions have been reported when morphine or other phenanthrene alkaloids of opium are administered intravenously.

The most frequently observed adverse reactions included sedation, lightheadedness, dizziness, nausea, vomiting, constipation, and diaphoresis.

DRUG INTERACTIONS

Clinically significant drug interactions can occur with the following drugs:

Benzodiazepines and Other Central Nervous System (CNS) Depressants: can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death.

Serotonergic Drugs: concomitant use has resulted in serotonin syndrome.

MAOIs: MAOI interactions with opioids may manifest as serotonin syndrome or opioid toxicity.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: May reduce the analgesic effect of Morphine Sulfate Injection and/or precipitate withdrawal symptoms.

Muscle Relaxants: Morphine may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.

Cimetidine: Concomitant administration reported to precipitate apnea, confusion, and muscle twitching.

Diuretics: Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone.

Anticholinergic Drugs: Concomitant use may increase risk of urinary retention and/or severe constipation, which may lead to paralytic ileus.

Oral $P2Y_{12}$ Inhibitors: Co-administration with oral $P2Y_{12}$ inhibitors can decrease the absorption and peak concentration of oral $P2Y_{12}$ inhibitors and delay the onset of the antiplatelet effect.

USE IN SPECIFIC POPULATIONS

Pregnancy: *Labor or Delivery* - Opioids cross the placenta and may produce respiratory depression and psychophysiologic effects in neonates.

Lactation: Morphine is present in breast milk. Withdrawal symptoms can occur in breastfed infants when maternal administration of morphine is stopped, or when breastfeeding is stopped.

Females and Males of Reproductive Potential: Use for an extended period of time may cause reduced fertility in patients of reproductive potential.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Pharmacodynamic effects in the elderly are more variable than in the younger population. Respiratory depression is the chief risk and has occurred after large initial doses were administered to non-opioid-tolerant patients or when co-administered with other agents that depress respiration.

Hepatic and Renal Impairment: Morphine pharmacokinetics have been reported to be significantly altered in patients with cirrhosis and altered in those with renal failure.

DRUG DEPENDENCE

Both tolerance and physical dependence can develop during use. Morphine Sulfate Injection should not be abruptly discontinued in a physically dependent patient as a withdrawal syndrome may occur.

OVERDOSAGE

Acute overdose can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations.

INDICATIONS AND USAGE

Morphine Sulfate Injection, is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use
Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve Morphine Sulfate Injection for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia

Morphine Sulfate Injection should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

HOW SUPPLIED/STORAGE AND HANDLING

Morphine Sulfate Injection, USP is supplied as a sterile solution in single-dose 1 mL prefilled syringes for intravenous administration as follows:

2 mg/mL packaged in 10s (NDC 0641-6191-10)
4 mg/mL packaged in 10s (NDC 0641-6192-10)

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature] until ready to use. **PROTECT FROM LIGHT**. **DO NOT FREEZE**. Contains no preservative or antioxidant. DISCARD ANY UNUSED PORTION. DO NOT HEAT-STERILIZE.

ENDING INFORMATION

Patient Counseling Information should be shared with the patient prior to administration.
For additional Important Safety 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.

For Product Inquiry call 1-877-845-0689.

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

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