



Dilaudid® (HYDRORmorphone Hydrochloride) Injection, USP

0.2 mg per 1 mL, 0.5 mg per 0.5 mL,
1 mg per 1 mL and 2 mg per 1 mL Simplist®
ready-to-administer prefilled syringes available
from Fresenius Kabi

Manufacturer prepared

24- to 36-month shelf life

Preservative free

MicroVault® tamper-evident packaging

Dilaudid (HYDRORmorphone Hydrochloride) Injection, USP

INDICATIONS AND USAGE

DILAUDID INJECTION is indicated for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate:

Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve DILAUDID INJECTION for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

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

IMPORTANT SAFETY INFORMATION:

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS
See full prescribing information for complete boxed warning.

- DILAUDID INJECTION exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions.

- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.**

- **Prolonged use of DILAUDID INJECTION during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.**

- **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 for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.**

DILAUDID INJECTION is contraindicated in patients with:

- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus.

- Known hypersensitivity to hydromorphone, hydromorphone salts, sulfite-containing medications, or any other components of the product.

Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely during initiation and titration.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of DILAUDID INJECTION in patients with circulatory shock.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of DILAUDID INJECTION in patients with impaired consciousness or coma.

DILAUDID INJECTION contains sodium metabisulfite. There is a risk of anaphylactic symptoms and life-threatening asthmatic episodes in susceptible people.

Most common adverse reactions are lightheadedness, dizziness, sedation, nausea, vomiting, sweating, flushing, dysphoria, euphoria, dry mouth, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue DILAUDID INJECTION if serotonin syndrome is suspected.

Monoamine Oxidase Inhibitors (MAOIs): Can potentiate the effects of hydromorphone. Avoid concomitant use in patients receiving MAOIs or within 14 days of stopping treatment with an MAOI.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with DILAUDID INJECTION because they may reduce analgesic effect of DILAUDID INJECTION or precipitate withdrawal symptoms.

Pregnancy: May cause fetal harm.

Overdosage: Acute overdose with DILAUDID INJECTION 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.

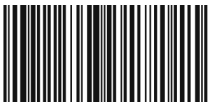



This Important Safety Information does not include all the information needed to use DILAUDID safely and effectively. Please see the full prescribing information, including BOXED WARNING, for DILAUDID INJECTION at www.simplist-us.com.

Dilaudid®

(HYDROmorphine Hydrochloride) Injection, USP

Market exclusive



Strength	0.2 mg per 1 mL	0.5 mg per 0.5 mL	1 mg per 1 mL	2 mg per 1 mL
Concentration	0.2 mg per 1 mL	0.5 mg per 0.5 mL	1 mg per 1 mL	2 mg per 1 mL
Fill volume	1 mL	0.5 mL	1 mL	1 mL
Unit of sale NDC	76045-121-11	76045-009-06	76045-009-11	76045-010-11
Unit of sale bar code	 N(01)3037604512118	 N(01)30376045009065	 N(01)30376045009119	 N(01)30376045010115
Pack size	10 per Carton (Bundles of 5)	10 per Carton (Bundles of 5)	10 per Carton (Bundles of 5)	10 per Carton (Bundles of 5)
MicroVault® dimensions	3.625" x .75"	3.625" x .75"	3.625" x .75"	3.625" x .75"
Carton dimensions	3.125" x 2.625" x 4.375"	3.125" x 2.625" x 4.375"	3.125" x 2.625" x 4.375"	3.125" x 2.625" x 4.375"
Wholesale numbers				
AmerisourceBergen	10235736	10228908	10228930	10228813
Cardinal	5645064	5553110	5553128	5553136
McKesson	1539311	3972452	3972494	3972502
Morris & Dickson	903609	762484	762526	762690

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