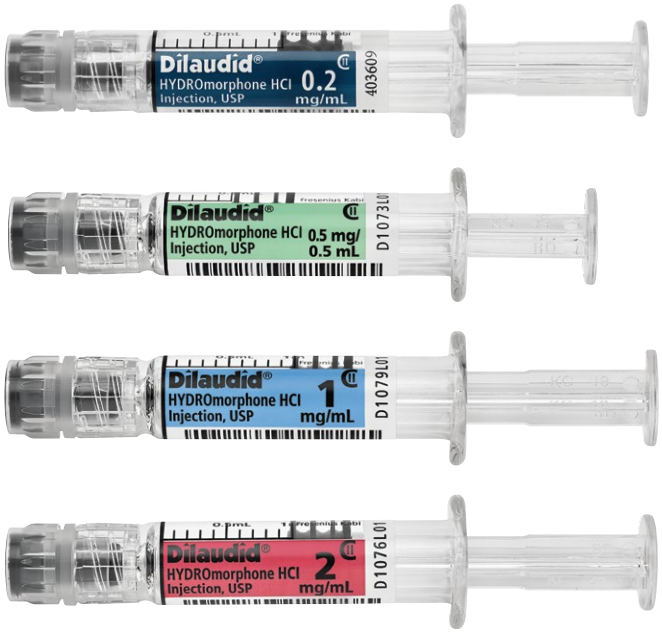
FRESENIUS KABI



Dilaudid®

(HYDROmorphone Hydrochloride) Injection, USP

0.2 mg per mL, 0.5 mg per 0.5 mL,
1 mg per mL and 2 mg per 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 (HYDROmorphone Hydrochloride) Injection, USP

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

Addiction, Abuse, and Misuse

DILAUDID 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 DILAUDID INJECTION and monitor 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 DILAUDID INJECTION. Monitor for respiratory depression, especially during initiation of DILAUDID INJECTION or following a dose increase.

Neonatal Opiod Withdrawal Syndrome

Prolonged use of DILAUDID INJECTION during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

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 or DILAUDID Injection and benzodiazepines or other CNS depressants for use 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.**

INDICATIONS AND USAGE

DILAUDID® INJECTION (hydromorphone hydrochloride), for intravenous, intramuscular, or subcutaneous use, is an opioid agonist 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

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.

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse.

Warnings and Precautions:

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

Adverse Reactions: 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.

Serotenergic 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 INJECTION safely and effectively. Please see full prescribing information for DILAUDID INJECTION, including BOXED WARNING, at www.simplist-us.com.

Simplist®

Dilaudid®
(HYDROmorphone Hydrochloride) Injection, USP

	Market exclusive			
				
Strength	0.2 mg per mL	0.5 mg per 0.5 mL	1 mg per mL	2 mg per mL
Concentration	0.2 mg per mL	0.5 mg per 0.5 mL	1 mg per mL	2 mg per 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)30376045121181	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				
Cardinal	5645064	5553110	5553128	5553136
Cencora	10235736	10228908	10228930	10228813
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

FRESENIUS KABI

Fresenius Kabi USA, LLC
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Please see package insert for full prescribing information at www.simplist-us.com.