NOW AVAILABLE

Simplist® Dilaudid Packaging Transition

MicroVault™

New packaging features a smaller size and secure dispensing

Simplist®
Ready-to-administer prefilled syringes

FRESENIUS KABI
caring for life

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, 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 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 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.

Additional serious adverse reactions: Apnea, circulatory depression, respiratory arrest, shock, cardiac arrest, seizures, withdrawal, anaphylaxis. Most common adverse reactions: 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, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Overdosage: Acute overdose can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, miosis (or mydriasis when hypoxia is present), and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring, and death.

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

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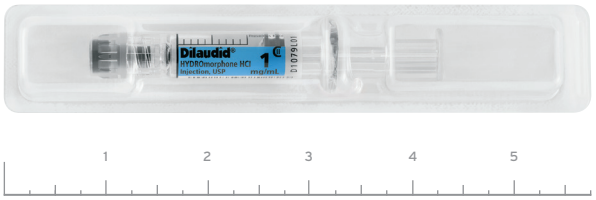
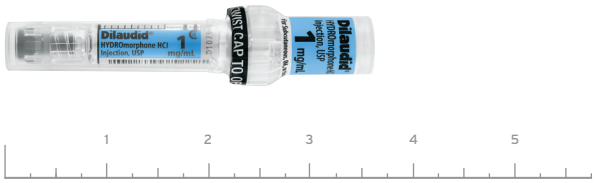
MicroVault™

New packaging features a smaller size and secure dispensing

NOW AVAILABLE



Blister dimensions: 5.75" x 1"



MicroVault™ dimensions: 3.625" x .75"

Blister

CURRENT

STRENGTH	NDC (UNIT OF USE)
Dilaudid 0.5 mg/0.5 mL	76045-009-03
Dilaudid 1 mg/mL	76045-009-00
Dilaudid 2 mg/mL	76045-010-00

MicroVault™

NOW AVAILABLE

STRENGTH	NDC (UNIT OF USE)
Dilaudid 0.5 mg/0.5 mL	76045-009-96
Dilaudid 1 mg/mL	76045-009-01
Dilaudid 2 mg/mL	76045-010-01

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MicroVault™ Carton

Featuring a smaller 10-pack carton for easier inventory management

Blister carton dimensions: 6.5" x 2.125" x 6.25"

MicroVault™ carton dimensions: 3.125" x 2.625" x 4.375"

Blister Carton

CURRENT

- 24-pack carton
- Packaged in blisters

STRENGTH	NDC (UNIT OF SALE)
Dilaudid 0.5 mg/0.5 mL	76045-009-05
Dilaudid 1 mg/mL	76045-009-10
Dilaudid 2 mg/mL	76045-010-10

MicroVault™ Carton

NOW AVAILABLE

- 10-pack carton
- Packaged in bundles of 5

STRENGTH	NDC (UNIT OF SALE)
Dilaudid 0.5 mg/0.5 mL	76045-009-06
Dilaudid 1 mg/mL	76045-009-11
Dilaudid 2 mg/mL	76045-010-11

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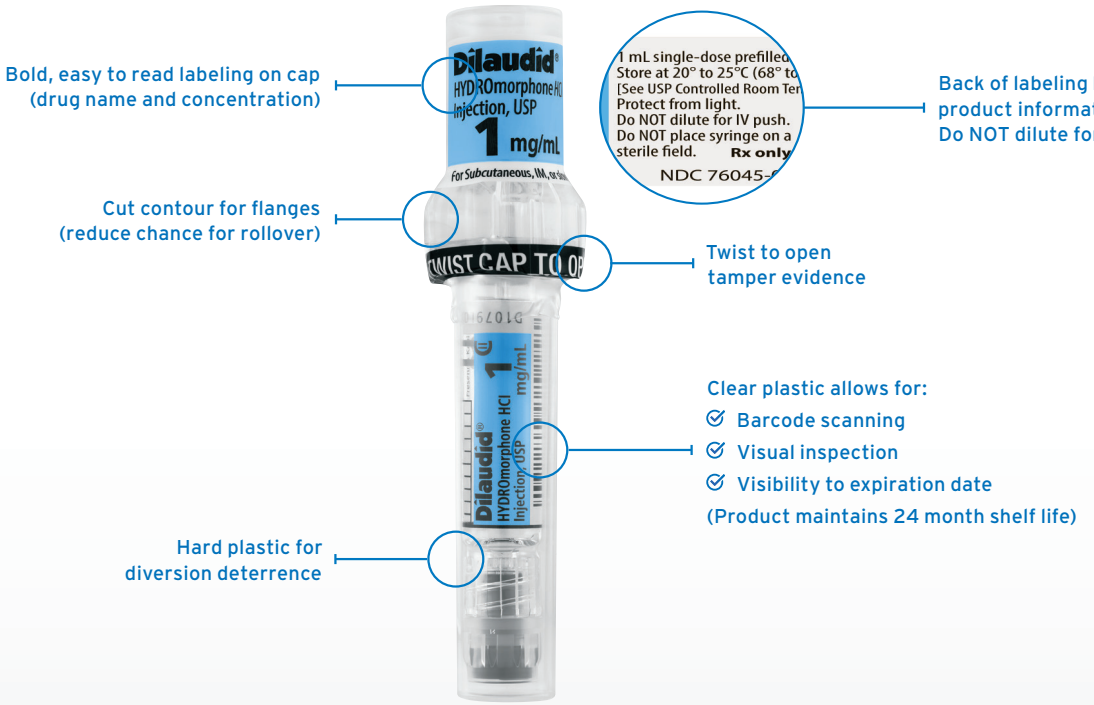

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www.fresenius-kabi.com/us | 1.888.386.1300

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