Simbadol
(buprenorphine injection)

1.8 mg/mL

For subcutaneous use in cats

**BRIEF SUMMARY:** Before using SIMBADOL, please consult the full prescribing information, a summary of which follows.

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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**HUMAN SAFETY WARNING**

**Abuse Potential**

SIMBADOL contains buprenorphine (1.8 mg/mL), an opioid agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. Buprenorphine has certain opioid properties that in humans may lead to dependence of the morphine type. Abuse of buprenorphine may lead to physical dependence or psychological dependence. The risk of abuse by humans should be considered when storing, administering and disposing of SIMBADOL. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (suicidal depression).

**Life-Threatening Respiratory Depression**

Respiratory depression, including fatal cases, may occur with abuse of SIMBADOL.

**Additive CNS Depressant Effects**

SIMBADOL has additive CNS depressant effects when used with alcohol, other opioids, or illicit drugs that cause central nervous system depression.

**Accidental Exposure**

Because of the potential for adverse reactions associated with accidental injection, SIMBADOL should only be administered by veterinarians or veterinary technicians who are trained in the handling of potent opioids.

See Human Safety for detailed information.

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**INDICATION:** SIMBADOL is indicated for the control of postoperative pain associated with surgical procedures in cats.

**DOSE AND ADMINISTRATION:** The dosage of SIMBADOL is 0.24 mg/kg (0.11 mg/lb) administered subcutaneously once daily, for up to 3 days. Administer the first dose approximately 1 hour prior to surgery. Do not dispense SIMBADOL for administration at home by the pet owner (see Human Safety).

**CONTRAINDICATIONS:** SIMBADOL is contraindicated in cats with known hypersensitivity to buprenorphine hydrochloride or any of the components of SIMBADOL, or known intolerance to opioids.

**WARNINGS:** For subcutaneous (SQ) injectable use in cats.

**Human Safety: Not for use in humans. Keep out of reach of children.**

Because of the potential for adverse reactions, hospital staff should avoid accidental exposure and contact with skin, eyes, oral or other mucous membrane during administration. SIMBADOL contains buprenorphine, a mu opioid partial agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. SIMBADOL can be abused and is subject to misuse, abuse, addiction and criminal diversion. SIMBADOL should be handled appropriately to minimize the risk of diversion, including restriction of access, the use of accounting procedures, and proper disposal methods, as appropriate to the clinical setting and as required by law. Abuse of SIMBADOL poses a hazard of overdose and death. This risk is increased with concurrent abuse of alcohol and other substances including other opioids and benzodiazepines. Buprenorphine has been diverted for non-medical use into illicit channels of distribution. All people handling opioids require careful monitoring for signs of abuse. Drug abuse is the intentional non-therapeutic use of a prescription drug for its rewarding psychological or physiological effects. Abuse of opioids can occur in the absence of true addiction. Naloxone may not be effective in reversing respiratory depression produced by buprenorphine. The onset of naloxone effect may be delayed by 30 minutes or more. Doxapram hydrochloride has also been used as a respiratory stimulant.

**PRECAUTIONS:** Hyperactivity (opioid excitation) has been observed up to 8 hours after anesthetic recovery (see ADVERSE REACTIONS). Safety has not been evaluated in moribund cats. Use in such cases should be based on the risk-benefit assessment of the veterinarian. Use with caution in cats with impaired hepatic function. The use of SIMBADOL has not been evaluated in breeding, pregnant, or lactating cats, or in cats younger than 4 months of age.

**ADVERSE REACTIONS:** In two controlled field studies, the following adverse reactions were reported.

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### Adverse Reactions in Two Field Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>SIMBADOL (N = 224)</th>
<th>Control (N = 226)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension a</td>
<td>68 (30.4%)</td>
<td>51 (22.8%)</td>
</tr>
<tr>
<td>Tachycardia b</td>
<td>55 (24.6%)</td>
<td>73 (32.6%)</td>
</tr>
<tr>
<td>Hypothermia (≤98°F)</td>
<td>38 (17.0%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Hypothermia (≥103.0°F)</td>
<td>1 (0.4%)</td>
<td>91 (40.6%)</td>
</tr>
<tr>
<td>Hypertension a</td>
<td>10 (4.5%)</td>
<td>40 (17.9%)</td>
</tr>
<tr>
<td>Anorexia</td>
<td>0 (0.0%)</td>
<td>40 (17.9%)</td>
</tr>
<tr>
<td>Hyperactivity b</td>
<td>0 (0.0%)</td>
<td>26 (11.6%)</td>
</tr>
<tr>
<td>Reduced SpO2 (≤90%)</td>
<td>8 (3.6%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Bradycardia (≤90 beats/min)</td>
<td>5 (2.2%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Tachypnea (≥72 breaths/min)</td>
<td>0 (0.0%)</td>
<td>5 (2.2%)</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>1 (0.4%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Blindness</td>
<td>0 (0.0%)</td>
<td>2 (0.9%)</td>
</tr>
<tr>
<td>Apnea/Death</td>
<td>1 (0.4%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Ataxia</td>
<td>0 (0.0%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Hyperesthesia a</td>
<td>0 (0.0%)</td>
<td>1 (0.4%)</td>
</tr>
</tbody>
</table>

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a. Cats may have experienced more than one type or occurrence of an adverse reaction. Cats experiencing the same reaction both during and after surgery are presented in both time periods.

b. During surgery is the time from the administration of the anesthetic induction agent until discontinuation of the gas anesthetic.

c. Hypotension is defined as a mean blood pressure of ≤60 mmHg during surgery and ≤90 mmHg after surgery.

d. Tachycardia is defined as a heart rate of ≥180 beats per minute during surgery and ≥200 beats per minute after surgery.

e. Hypertension is defined as a mean blood pressure of ≥120 mmHg during surgery and ≥160 mmHg after surgery.

To report suspected adverse events, contact Abbott Animal Health at 1-888-299-7416, FDA at 1-888-FDA-VETS or FDA online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

**EFFECTIVENESS:** The effectiveness of SIMBADOL was demonstrated in two randomized, masked, placebo-controlled, multi-site field studies involving client-owned cats of various breeds. A descriptive, interactive pain assessment system was used by the trained assessor over the 72-hour post-operative period to determine pain control, and treatment success was defined as a cat that completed the 72-hour post-operative period without rescue analgesia. A statistically significant difference (P ≤ 0.005) in the number of successes in the treatment group over the placebo control group was observed. The results of two field studies demonstrate that SIMBADOL is effective and has an acceptable safety margin for the control of postoperative pain in cats.

**HOW SUPPLIED:** SIMBADOL (buprenorphine injection) is supplied in a carton containing one 10 mL amber glass vial. Each multidose vial contains 1.8 mg/mL of buprenorphine.

NADA 141-434, Approved by FDA

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Product of United Kingdom

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