SIMBADOL (buprenorphine injection)
Frequently Asked Questions

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1. What is SIMBADOL?
   A: SIMBADOL is a proprietary, FDA-approved, veterinary-labeled buprenorphine formulation indicated for the control of postoperative pain associated with surgical procedures in cats. SIMBADOL has been shown to be effective for 24 hours at a subcutaneous (SQ) dose of 0.24 mg/kg.

2. What is the recommended dosage of SIMBADOL?
   A: The recommended dosage of SIMBADOL is 0.24 mg/kg.

3. How is SIMBADOL administered?
   A: SIMBADOL is administered subcutaneously.

4. How many doses will one vial provide?
   A: One vial provides approximately 15 doses based on an average cat weight of 5 kg, which equates to a dose volume of 0.67 mL for each 5 kg cat.

5. Can I send SIMBADOL home with the pet owners, so they can administer it to their cats?
   A: No. SIMBADOL should be used by a licensed veterinarian or member of the staff on the order of a licensed veterinarian. The label reads: **Do not dispense the drug for administration at home by the pet owner, due to serious human safety and abuse concerns, including physical or psychological dependence, life-threatening respiratory depression and additive CNS depressant effects. Read the entire package insert before using this drug, including the complete Boxed Human Safety Warning.**

6. What is the DEA schedule for SIMBADOL?
   A: As with other formulations of buprenorphine, SIMBADOL is Class III, controlled substance.

7. What if the cat is being sent home on the same day of surgery and requires additional days of analgesia for the pet owners to administer at home?
   A: If the cat requires additional days of analgesia for at-home administration by the owner, pain management is at the discretion of the veterinarian based on the assessment of each individual patient and would be consistent with their typical pain management protocols. Various medications can be sent home, however, veterinarians **should not send SIMBADOL home with the pet owner** due to potential for human abuse or accidental exposure.
General Use Questions

1. What is SIMBADOL?
   A: SIMBADOL is a proprietary, FDA-approved, veterinary-labeled buprenorphine formulation indicated for the control of postoperative pain associated with surgical procedures in cats. SIMBADOL has been shown to be effective for 24 hours at a subcutaneous (SQ) dose of 0.24 mg/kg.

2. What is the recommended dosage of SIMBADOL?
   A: The recommended dosage of SIMBADOL is 0.24 mg/kg.

3. How is SIMBADOL administered?
   A: SIMBADOL is administered subcutaneously.

4. When should the first dose of SIMBADOL be given to the patient?
   A: The first dose should be administered approximately 1 hour prior to surgery. Onset of analgesia is approximately 1 hour after administration and continues for 24 hours.

5. Can I administer SIMBADOL less than or more than an hour before surgery?
   A: Clinical studies found that the onset of analgesia was about 1 hour. Dosage recommendations are to administer approximately 1 hour prior to surgery.

6. When can the patient receive the second and third doses of SIMBADOL?
   A: The patient can receive the second dose 24 hours after the first dose, and receive the third dose 24 hours after the second dose to provide up to 72 hours of postoperative analgesia.

7. How many doses will one vial provide?
   A: One vial provides approximately 15 doses based on an average cat weight of 5 kg, which equates to a dose volume of 0.67 mL for each 5 kg cat.

8. Can I send SIMBADOL home with the pet owner, so they can administer it to their cats?
   A: No. SIMBADOL should be used by a licensed veterinarian or member of the staff on the order of a licensed veterinarian. The label reads: Do not dispense the drug for administration at home by the pet owner, due to serious human safety and abuse concerns, including physical or psychological dependence, life-threatening respiratory depression and additive CNS depressant effects. Read the entire package insert before using this drug, including the complete Boxed Human Safety Warning.

9. What is the DEA schedule for SIMBADOL?
   A: As with other formulations of buprenorphine, SIMBADOL is Class III, controlled substance.
10. Can I use SIMBADOL in dogs, pocket pets, exotic species or laboratory species?  
   A: No. There are no data to support the use of SIMBADOL in dogs or other species.

11. Will SIMBADOL have a dose sparing effect?  
   A: The dose sparing effects of SIMBADOL were not evaluated in the clinical field studies.

12. How do I incorporate SIMBADOL into my current anesthesia protocols?  
   A: Although not specifically evaluated in the clinical field studies, it is reasonable to expect that SIMBADOL can be included in routine protocols using the following considerations:  
   a) If acepromazine is used as a premedication, administer SIMBADOL 1 hour prior to surgery at the same time as acepromazine, but administer in a separate syringe.  
   b) If used with a premedication of dexmedetomidine or dexmedetomidine and ketamine, administer SIMBADOL 1 hour prior to surgery then administer the other premedication(s) at a dosage, timing and route consistent with current protocols.

13. What is the benefit of using SIMBADOL over butorphanol?  
   A: SIMBADOL has a longer duration of analgesia and may be a more potent analgesic when compared to butorphanol. However, there are no studies directly comparing the effects of SIMBADOL to butorphanol.

14. Are there any drugs that are contraindicated for concurrent use with SIMBADOL?  
   A: There are currently no drugs that are contraindicated for use with SIMBADOL.

15. Does SIMBADOL cause sedation and/or excitation?  
   A: Some cats experienced sedation for up to 4 hours and excitation for up to 8 hours after surgery.

16. Do I need to adjust the dosage of SIMBADOL for a cat with liver or kidney disease? If so, how do I adjust the dosage?  
   A: Since SIMBADOL is metabolized by the liver and excreted in the bile, use with caution in cats with impaired hepatic function. SIMBADOL has not been evaluated in cats with renal disease, but is not excreted in the urine.

17. Can I use SIMBADOL with an NSAID?  
   A: Studies have not been conducted to assess the safety of SIMBADOL when used in combination with NSAIDs and/or other analgesics in cats, although cats that required rescue in the clinical efficacy study were administered meloxicam. Management of rescue in the clinical efficacy study was at the discretion of the attending veterinarian based on the assessment of each individual patient.
18. Is the use of SIMBADOL contraindicated when used in combination with other opioids in cats?

A: Studies have not been conducted to assess the safety of SIMBADOL when used in combination with other opioids in cats, although some cats received hydromorphone as a rescue analgesic in the clinical field study. Management of pain is at the discretion of the attending veterinarian based on the assessment of each individual patient.

19. Does SIMBADOL affect appetite?

A: In the clinical field study, anorexia was reported as an adverse event for 16.5-19.1% of cats that received SIMBADOL. This was similar to the placebo control group where 13.4-17.5% of the cats experienced anorexia. In the target animal safety study, cats in the 1x (0.24 mg/kg) and 3x (0.72 mg/kg) groups had increased appetite and gained weight, whereas the cats in the 5x (1.2 mg/kg) group had a decreased appetite and lost weight.

20. What if the cat is being sent home on the same day of surgery and requires additional days of analgesia for the pet owners to administer at home?

A: If the cat requires additional days of analgesia for at-home administration by the owner, pain management is at the discretion of the veterinarian based on the assessment of each individual patient and would be consistent with their typical pain management protocols. Various medications can be sent home, however, veterinarians should not send SIMBADOL home with the pet owner due to potential for human abuse or accidental exposure.

Efficacy Questions

1. What data confirms 24 hours of analgesia?

A: The 24-hour duration of postoperative analgesia was confirmed in two large field studies involving more than 200 cats undergoing soft tissue and/or orthopedic surgeries.

2. How many cats were involved in the soft tissue surgery study?

A: There were 109 cats treated with SIMBADOL, and 112 cats treated with a placebo in the soft tissue study.
3. What types of surgeries were included in the soft tissue surgery study?
   A: The following table summarizes the various types of surgeries conducted in this study:

<table>
<thead>
<tr>
<th>Surgery Type</th>
<th>No. Placebo Treated Cats</th>
<th>No. SIMBADOL Treated Cats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovariohysterectomy</td>
<td>49</td>
<td>41</td>
</tr>
<tr>
<td>Lumpectomy</td>
<td>18</td>
<td>22</td>
</tr>
<tr>
<td>Perineal urethrostomy</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Cystotomy</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Enucleation</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Herniorrhaphy</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Herniorrhaphy</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Blepharoplasty</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Exploratory laparotomy</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Other procedures*</td>
<td>11</td>
<td>9</td>
</tr>
</tbody>
</table>

*Other surgeries include thyroidectomy, ear hematoma

4. How was efficacy assessed in the soft tissue surgery study?
   A: The primary efficacy end point was the rate of treatment success, defined as those cats not requiring additional analgesia during the 72-hour observation period.

5. What was the efficacy in the soft tissue surgery study?
   A: Efficacy or treatment success was 71% for the cats treated with SIMBADOL—meaning 71% of the SIMBADOL cats did not require additional analgesia during the 72-hour observation period. This was significantly different (p=0.005) than the placebo-treated cats, where 44% did not require additional analgesia during the 72-hour observation period.

6. How many cats were involved in the orthopedic surgery study?
   A: There were 115 SIMBADOL-treated cats and 114 placebo-treated cats in the orthopedic study.

7. What types of surgeries were included in the orthopedic surgery study?
   A: The types of surgeries are summarized in the following table:

<table>
<thead>
<tr>
<th>Type of Surgery</th>
<th>% of Cats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onychectomy surgery only</td>
<td>62%</td>
</tr>
<tr>
<td>Onychectomy and ovariohysterectomy</td>
<td>22.7%</td>
</tr>
<tr>
<td>Onychectomy and orchietomy</td>
<td>15.3%</td>
</tr>
</tbody>
</table>

8. How was efficacy assessed in the orthopedic surgery study?
   A: The primary efficacy end point was the rate of treatment success defined as those cats not requiring additional analgesia during the 72-hour observation period.
9. What was the efficacy in the orthopedic surgery study?
   A: Efficacy or treatment success was 61% for the cats treated with SIMBADOL - meaning 61% of the SIMBADOL cats did not require additional analgesia during the 72-hour observation period. This was significantly different (p=0.002) than the placebo-treated cats where 32% did not require additional analgesia during the 72-hour observation period.

10. Why was analgesia provided for only 72 hours postoperatively?
    A: When developing the protocols for the clinical efficacy studies, it was determined in conversations with the FDA that an appropriate duration for postoperative analgesia for soft tissue and orthopedic surgeries (onchyectomy) was 72 hours. Therefore, with 24-hour duration of analgesia, 3 doses of SIMBADOL were administered to assess efficacy and safety over the 72-hour postoperative period.

11. What was the anesthesia protocol used in clinical studies?
    A: Cats enrolled in the clinical field study were given acepromazine (0.05 mg/kg SC), plus or minus glycopyrrolate (0.005 mg/kg SC) preoperatively, approximately 1 hour prior to surgery, at the same time as the study drug (either saline or SIMBADOL). The decision to administer glycopyrrolate was at the discretion of the attending veterinarian. The premedicants were administered in a separate syringe than the study drug. Cats were induced with propofol and maintained with isoflurane or sevoflurane. During surgery, intravenous fluids were administered at the discretion of the attending veterinarian.

12. Why was acepromazine used as the only other premedication?
    A: No other analgesics were used in the study so the analgesic effects of SIMBADOL could be properly evaluated without having to consider the effects of concurrent analgesic agents. A standardized rescue protocol was implemented for any cat that was perceived to be in pain, as assessed by the attending veterinarian.

13. What was the rescue protocol that was implemented in the clinical field studies?
    A: In order that the cats in the study not experience pain, a rescue protocol was implemented. If any cat required additional analgesia, meloxicam, at 0.1 mg/kg SQ, was administered and monitoring continued until the cat was considered comfortable. If pain was still evident after 1 hour of observation, hydromorphone (0.3 mg/kg SQ) was administered. In cases of extreme pain, meloxicam (0.1 mg/kg SQ) and hydromorphone (0.3 mg/kg SQ) were administered concurrently. If pain continued, the cat was treated based on the attending veterinarian’s judgment.
14. What is recommended if the cat requires more than 72 hours of analgesia postoperatively?
   A: If the feline patient requires more than 72 hours of analgesia postoperatively, other analgesic drugs can be considered including NSAIDS, other opioids, or a combination. The choice of analgesics is at the discretion of the attending veterinarian and should be consistent with the needs of the patient.

15. In the clinical study, propofol was used as the induction agent. Can I use other induction agents such as ketamine/diazepam or midazolam or Telazol® (tiletamine HCl and zolazepam (HCl))?
   A: Studies have not been conducted to assess the safety and efficacy of SIMBADOL when used with induction agents other than propofol. Choice of induction agent is at the discretion of the attending veterinarian.

IMPORTANT SAFETY INFORMATION: Do not use TELAZOL in dogs and cats with pancreatic disease, renal pathology or impairment of renal function, or severe cardiac or pulmonary dysfunction. Do not use for Caesarean section. Do not use phenothiazine-derivative drugs concomitantly with TELAZOL as the combination produces respiratory and myocardial depression, hypotension, and hypothermia. Pulmonary edema has been reported in cats. Respiratory depression may occur following administration of high doses of TELAZOL. See full Prescribing Information.

Safety Questions

1. How is SIMBADOL metabolized and excreted?
   A: SIMBADOL contains buprenorphine (1.8 mg/mL) which is metabolized in the liver. The major route of excretion of buprenorphine is in the feces. Buprenorphine undergoes oxidative metabolism by N-dealkylation to form norbuprenorphine (an active metabolite) via CYP3A. Buprenorphine and norbuprenorphine subsequently form inactive glucuronide conjugates in the intestinal wall and the liver, and its metabolites are excreted via the bile into the gastro-intestinal tract. The elimination half-life in cats is reported to be similar to that associated with humans, and slower than that observed in dogs. It is also noted that, because the cat is devoid of uridine diphosphate glucuronosyltransferase enzymes, conjugated metabolites may be absent.

2. Can I use SIMBADOL IV? IM? Transmucosally? CRI?
   A: No. There are no data to support the use of SIMBADOL for 24 hours continuous control of postoperative pain associated with surgical procedures in cats as an IV or IM injection, via transmucosal administration or as a CRI.

3. Is SIMBADOL safe to use in cats less than 16 weeks of age?
   A: SIMBADOL has not been evaluated in cats younger than 16 weeks of age.
4. Is there a minimum weight to consider when administering SIMBADOL?
   A: Cats in the clinical efficacy study weighed between 1.2 kg to 9 kg.

5. Is SIMBADOL safe to use in breeding, pregnant or nursing cats?
   A: SIMBADOL has not been evaluated in breeding, pregnant or nursing cats.

6. Is SIMBADOL painful on injection and/or are there any injection site reactions?
   A: SIMBADOL may cause pain on injection. In the Target Animal Safety study, the incidence of “moderate responses” (minor vocalization or wincing and quick resolution) and “severe responses” (tried to bite or scratch or had marked vocalization or persistent attention to the injection site) to injection was higher in the buprenorphine-treated group compared to the saline-treated group. Also, in the clinical field studies, the number of cats with pain on injection was higher in the SIMBADOL group (20 cats, 28 incidences) compared to the placebo group (8 cats, 10 incidences). Additionally, the pH of SIMBADOL is weakly acidic.

7. Can SIMBADOL cause an injection site sarcoma?
   A: It is not known if SIMBADOL can cause injection site sarcomas. Injection site evaluation was conducted in the Target Animal Safety studies, where SIMBADOL was administered at 1x, 3x, and 5x the label dose for 9 days. There was no clear dose-related effect associated with the injection site inflammation and severe inflammation was not noted for any of the SIMBADOL-treated cats. Note: Excipients used in SIMBADOL are similar to those commonly used for injectable drugs. There are no carriers, vehicles or matrixes that could be associated with depot injection type of effect.

8. What adverse events were reported in the clinical studies?
   A: In two controlled field studies, the most frequent adverse reactions with SIMBADOL were hypotension, tachycardia, hypothermia, hyperthermia, hypertension, anorexia, and hyperactivity. Rare, but serious adverse reactions included two deaths following apnea, one euthanasia and two reports of presumptive post-anesthetic blindness. One additional case of blindness was reported in the control group. Blindness was not considered to be associated with SIMBADOL; there was not a definitive association between the reported deaths and SIMBADOL use.

9. Dilated pupils and decreased pupillary light response has been reported postoperatively in cats that received SIMBADOL, can this be mistaken for blindness?
   A: Dilated pupils with reduced pupillary light response associated with opioid treatment may be mistaken as a temporary decrease in, or loss of vision because of decreased visual acuity. By monitoring patients and ensuring the cats are visual when the pupillary response returns to normal (typically within 24 hours after the last dose of SIMBADOL), the attending veterinarian can distinguish between normal opioid-associated dilated pupils and blindness.
10. Why did so many cats experience hyperactivity and/or hyperthermia?
   A: Hyperactivity and hyperthermia are known opioid responses experienced by feline patients.

11. Does SIMBADOL have any adverse effects on the cardiovascular system?
   A: Adverse cardiovascular events that occurred in the clinical field studies at a higher rate for the group treated with SIMBADOL verses the control group included hypertension and tachycardia. Hypotension, arrhythmias and bradycardia were also reported, but at the same rate as the control group.

12. What is the margin of safety for SIMBADOL?
   A: Although a higher-than-label dosage of SIMBADOL should not be administered, Target Animal Safety studies established a 5X margin of safety.

13. Are there any cats who should not receive SIMBADOL?
   A: Do not use SIMBADOL in any cats with a known reaction/hypersensitivity to buprenorphine hydrochloride, or any of the components of SIMBADOL, or known intolerance to opioids. The use of SIMBADOL has not been evaluated in breeding, pregnant, or lactating cats, or in cats younger than 4 months of age. Safety has not been evaluated in moribund cats (i.e., those not expected to live more than 24 hours with or without surgery). Use in such cases should be based on the risk: benefit assessment made by the veterinarian. Use with caution in cats with impaired hepatic function.

14. Is there a maximum volume that can be injected at one site?
   A: When dosed at the label dosage, given as a subcutaneous injection, the volume administered for cats of all sizes should be well tolerated as a single injection.

15. Is there a drug to reverse SIMBADOL in cats?
   A: No studies have been conducted to test drugs to reverse SIMBADOL in cats; however, naloxone is often used to reverse opioids. Use of naloxone to reverse SIMBADOL may take 30 minutes to have onset of effect and may only partially reverse the effects, requiring additional dosing at the discretion of the attending veterinarian.

16. Can SIMBADOL be used to treat chronic pain or non-surgical pain in a cat?
   A: SIMBADOL was evaluated for control of postoperative pain. There are no data to support use for chronic pain or non-surgical pain.

**Storage / Formulation Questions**

1. What is the expiration of SIMBADOL?
   A: At the time of manufacturing, each SIMBADOL vial has 21 months of shelf life.
2. What is the in-use shelf life of the injectable formulation of SIMBADOL once the vial has been broached?
   A: The in-use shelf life of the injectable formulation of SIMBADOL is 28 days once the vial has been broached, or from the day of first puncture. Record the date of first puncture on the vial.

3. Does SIMBADOL need to be refrigerated?
   A: No. SIMBADOL should be stored at temperatures up to 25°C (77°F) and should be protected from light and excessive heat (above 40°C or 104°F).

4. Can SIMBADOL be mixed with other anesthetic drugs in a syringe?
   A: Do not mix SIMBADOL with other anesthetic drugs in the same syringe, as studies have not been conducted to evaluate compatibility.

5. How many times can the vial be punctured, once broached, during the 28-day period?
   A: The in-use study supports up to 28 punctures/withdrawals with a 21 gauge needle.

6. Is SIMBADOL a sustained-release formulation of buprenorphine?
   A: No. SIMBADOL is an aqueous solution immediate-release product with no matrix. Onset of action is approximately 1 hour after administration.

7. How does SIMBADOL differ from the 0.3 mg/mL formulation of buprenorphine?
   A: SIMBADOL differs from the 0.3 mg/mL formulation of buprenorphine with a novel combination of dosage and concentration. SIMBADOL contains 1.8 mg/mL of buprenorphine and has been specifically formulated so that one dosage of 0.24 mg/kg administered subcutaneously will provide 24-hours of postoperative analgesia to a cat.

   SIMBADOL also differs from the 0.3 mg/mL formulation in that it is FDA-approved for cats, with substantial evidence of proven safety and efficacy in the cat. Although studies have been conducted to evaluate the 0.3 mg/mL formulation in cats, these studies involved only a small number of cats. At recommended dosages (0.02-0.03 mg/kg), one dose of 0.3 mg/mL formulation provides approximately 6-8 hours of analgesia. Additionally, these formulations are FDA-approved for use in humans but not in cats.

8. How does SIMBADOL differ from the compounded sustained-release formulation of buprenorphine?
   A: The compounded sustained-release buprenorphine formulation contains buprenorphine hydrochloride in a proprietary sustained-release biodegradable matrix, which acts as a depot at the site of injection. The buprenorphine in the compounded sustained-release formulation is not FDA-approved, and there is no reliable data to support the safe and effective use of this compounded sustained-
release substance. Additionally, no data exist to support stability of the sustained-release product after the vial has been broached. SIMBADOL, on the other hand, is stable for 28 days after the first dose has been withdrawn.

9. What are the implications of using a compounded drug?
A: Because a compounded product should be made based on a veterinarian’s prescription, the veterinarian is responsible for the safety and efficacy of the compounded drug.

Since the compounding pharmacy is not required to conduct pharmacokinetic, safety or efficacy studies, there is no way to tell if measures taken to compound a drug will affect the pharmacokinetics, safety or efficacy of the compounded drug. There are also no requirements for a compounding pharmacy to run stability studies; therefore, there is no way to determine how long the compounded product is stable after it is made or after the compounded product is first used. This lack of requirements also could mean that there can be variations in the safety, efficacy and stability between batches of the same compounded drug made from the same or different compounding pharmacies.

10. Why does SIMBADOL provide 24 hours of analgesia when the 0.3 mg/mL formulation only provides 6-8 hours of analgesia?
A: The proprietary formulation of SIMBADOL (1.8 mg/mL of buprenorphine hydrochloride) and the dosage of 0.24 mg/kg are unique to SIMBADOL. The exact reason for the longer duration of action has not been determined, but could be due to pharmacokinetics and pharmacodynamics:

- Pharmacokinetic Factors
  - Increased dose
  - Volume of distribution
  - Rate of metabolism
  - Enterohepatic recirculation
- Pharmacodynamic Factors
  - Affinity and avidity of buprenorphine for the opioid receptors

One or more of these factors may contribute to the long duration of action.

11. There are previously published articles stating that subcutaneous administration of buprenorphine is ineffective. How is SIMBADOL different?
A: Several authors have evaluated a different formulation (0.30 mg/mL) and a different dosage (0.02-0.03 mg/kg) of buprenorphine prior to market availability of SIMBADOL leading to this conclusion. Clinical studies have shown that a subcutaneous injection of SIMBADOL at 0.24 mg/kg provides 24 hours of post-surgical analgesia.
12. How does SIMBADOL compare to buprenorphine 0.3 mg/mL? Can I get the same effect if I dose at 0.24 mg/kg using the 0.3 mg/mL formulation?
   A: It is not known if a 0.24 mg/kg dosage of buprenorphine 0.3 mg/mL administered subcutaneously will provide the same 24 hours of analgesia as SIMBADOL. It is also unknown what side effects might be observed. Additionally, the volume for administration using a dosage of 0.24 mg/kg of the 0.3 mg/mL formulation would be 8 times the SIMBADOL dose volume.
   Example: SIMBADOL dose volume for a 5 kg cat = 0.67 mL
   Generic buprenorphine (0.3 mg/mL) @ 0.24 mg/kg = 0.72 mL/kg x 5 kg = 4 mL

13. What about administering SIMBADOL at 0.02-0.04 mg/kg dose for a shorter duration?
   A: We do not know what the efficacy of this approach would be.

14. What is the rate of absorption of SIMBADOL after subcutaneous injection in the cat?
   A: Formulated as an immediate-release product, buprenorphine is quickly absorbed after subcutaneous injection. Although, following subcutaneous injection in cats, there is considerable inter-cat variability in plasma concentration and pharmacokinetic parameters, pharmacological effects (e.g., mydriasis) may occur within several minutes after injection. In studies with SIMBADOL, analgesic effects of buprenorphine appeared about 1 hour after injection.

15. What can I expect if I use a lower dosage of SIMBADOL for postoperative analgesia?
   A: In a dose determination study, doses of 0.02 mg/kg, 0.06 mg/kg, 0.12 mg/kg or 0.24 mg/kg were administered to cats undergoing ovariohysterectomy or onychectomy. Rescue analgesia was required in 2/3 cats in the 0.02 mg/kg group, 2/9 cats in the 0.06 mg/kg group, and 4/9 cats in the 0.12 mg/kg and 4/25 cats in the 0.24 mg/kg group. Based on these data the dosage of 0.24 mg/kg was determined to be the dosage that most consistently provides 24 hours of analgesia.

IMPORTANT SAFETY INFORMATION: Due to serious human safety and abuse concerns, including physical or psychological dependence, life-threatening respiratory depression and additive CNS depressant effects, read the full prescribing information before using this drug, including the complete Boxed Warning. Not for use in humans. Hospital staff should be trained in the handling of potent opioids and should avoid accidental exposure. SIMBADOL has not been evaluated in breeding, pregnant, or lactating cats, in cats younger than 4 months of age or moribund cats. Do not use in cats with known hypersensitivity to buprenorphine hydrochloride or any of the components of SIMBADOL, or known intolerance to opioids. Use with caution in cats with impaired hepatic function. Adverse reactions may include hyperthermia, tachycardia, hypotension, hypertension, hypothermia, anorexia, and hyperactivity. For more safety information, refer to the full Prescribing Information.


Zoetis Study Report: Summary Report for In-Use Stability Study for Multi-Dose Buprenorphine Injection, 1.8 mg/mL. November 14, 2012. (10 mL Presentation)AAI Pharma