TELAZOL- tiletamine hydrochloride and zolazepam hydrochloride injection, powder, for solution
Zoetis Inc.

Telazol® CIII
(tiletamine and zolazepam for injection)

100 mg/mL total
(equivalent to 50 mg/mL tiletamine and 50 mg/mL zolazepam)
For Intramuscular and Intravenous injection in Dogs
For Intramuscular injection only in Cats

CAUTION

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

TELAZOL (tiletamine and zolazepam for injection) is a nonnarcotic, nonbarbiturate, injectable anesthetic agent for dogs and cats. Chemically, TELAZOL is a combination of equal parts by weight of base of tiletamine hydrochloride (2-[ethylamino]-2-[2-thienyl]-cyclohexanone hydrochloride), an arylaminocycloalkanone dissociative anesthetic, and zolazepam hydrochloride (4-[o-fluorophenyl]-6, 8-dihydro-1,3,8- trimethylpyrazolo [3, 4-e][1,4] diazepin-7 [1H]-1- hydrochloride), a nonphenothiazine diazepinone having minor tranquilizing properties. The product is supplied sterile in vials. The addition of 5 mL diluent produces a solution containing the equivalent of 50 mg tiletamine base, 50 mg zolazepam base and 57.7 mg mannitol per milliliter. This solution has a pH of 2 to 3.5 and is recommended for deep intramuscular injection.

INDICATIONS

Dogs

TELAZOL is indicated in dogs for restraint and minor procedures of short duration (30 min. avg.) requiring mild to moderate analgesia. Minor surgery is considered to be laceration repair, draining of abscesses, castrations and other procedures requiring mild to moderate analgesia. (See Dogs under Dosage and Administration.) TELAZOL administered intravenously is indicated in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

Cats

TELAZOL is indicated in cats for restraint or for anesthesia combined with muscle relaxation.

DOSAGE AND ADMINISTRATION

The dose is determined by the total combined concentration of 100 mg/mL

(see HOW SUPPLIED)

Dogs

Intramuscular (IM) For Restraint and Minor Procedures of Short Duration Requiring Mild to Moderate Analgesia:

In healthy dogs, an initial intramuscular dosage of 3 to 4.5 mg/lb (6.6 to 9.9 mg/kg) TELAZOL is recommended for diagnostic purposes; 4.5 to 6 mg/lb (9.9 to 13.2 mg/kg) for minor procedures of short duration, such as treatment of lacerations and wounds, castrations and other procedures requiring mild to moderate analgesia. When supplemental doses of TELAZOL are required, such individual supplemental doses should be less than the initial dose, and the total dose given (initial dose plus supplemental dose or doses) should not exceed 12 mg/lb (26.4 mg/kg). The maximum safe dose is 13.6 mg/lb (29.92 mg/kg). (See Animal Safety.) Results from TELAZOL anesthesia in dogs will be more satisfactory if the procedures are completed within one hour and if the procedures can be completed following single dose administration. In order to maintain at least a 2X margin of safety in dogs, the use of this product is limited to procedures that call for low doses (see Indications). Studies show that there is variation in response to different dosages of TELAZOL and that low doses do not give adequate levels of anesthesia, and in some instances do not give adequate analgesia, for extensive procedures.

Intravenous (IV) For Induction of Anesthesia Followed by Maintenance with an Inhalant Anesthetic:

In dogs, for induction of anesthesia, administer TELAZOL intravenously at 1-2 mg/lb (2.2-4.4 mg/kg) body weight to effect. TELAZOL should be administered slowly, over 30-45 seconds; after approximately 30-60 seconds, the dog’s level of consciousness, muscle relaxation, and jaw tone should be assessed to determine the ability to intubate. If after waiting 60 seconds the dog’s level of anesthesia is not sufficient for successful intubation, additional TELAZOL may be administered; the total dose should not exceed 2 mg/lb (4.4 mg/kg) body weight.

Cats

In healthy cats, an initial TELAZOL dosage of 4.4 to 5.4 mg/lb (9.7 to 11.9 mg/kg) IM is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal and related types of surgery; 4.8 to 5.7 mg/lb (10.6 to 12.5 mg/kg) for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg/lb (14.3 to 15.8 mg/kg) are recommended for ovario hysterectomy and onychectomy. When supplemental doses of TELAZOL are required, such individual supplemental doses should be given in increments that are less than the initial dose, and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg/lb (72 mg/kg). (See Animal Safety.)

General Dosing Information

Fasting prior to induction of general anesthesia with TELAZOL is not essential; however, when preparing for elective surgery, it is advisable to withhold food for at least 12 hours prior to TELAZOL administration. As with other injectable anesthetic agents, the individual response to TELAZOL is somewhat varied, depending upon the dose, general physical condition and age of the patient, duration of the surgical procedure, and any preanesthetics used. Therefore, recommendations for dosage regimens cannot be fixed absolutely. Specific dosage requirements must be determined by evaluation of the health status and condition of the patient and of the procedure to be performed.
Recovery varies with the age and physical condition of the animal and the dose of TELAZOL administered. Recovery is extended with high dose or multiple injections, particularly in cats.

Intramuscular injection in dogs and cats:
There may be pain on injection. This is especially prevalent in cats.
Following a single, deep intramuscular injection of TELAZOL in cats and dogs, onset of anesthetic effect usually occurs within 5 to 12 minutes. Muscle relaxation is optimum for approximately the first 20 to 25 minutes after TELAZOL is

administered, and then diminishes.
Repeated doses increase the duration of the effect of TELAZOL but may not further diminish muscle tone. The quality of anesthesia with repeated doses varies because the ratio of the two components within the animal's body changes with each injection. This is due to the difference in the rates of metabolism and elimination of the two components. The quality of anesthesia will be improved and more predictable if the entire dose is given as a single injection rather than in several doses. The best method of evaluating the depth of TELAZOL anesthesia is to monitor the patient for deliberate conscious response to nociceptive stimuli.
If adequate anesthesia is not produced by the recommended dosage regimen, supplemental anesthesia or another agent is indicated. This includes the use of barbiturates and volatile anesthetics. When used concurrently with TELAZOL the dosage of these agents should be reduced.

PREPARATION OF SOLUTION FOR ADMINISTRATION

To each vial add 5 mL sterile water for injection, USP. Slight agitation will facilitate complete reconstitution. The resultant solution will contain 100 mg total TELAZOL per one milliliter (50 mg tiletamine and 50 mg zolazepam per mL).
Discard unused solution after 7 days when stored at room temperature or after 56 days when kept refrigerated. Only use clear solution. Color of solution may vary from colorless to light amber.

CONTRAINDICATIONS

The use of TELAZOL is contraindicated in dogs and cats with pancreatic disease. TELAZOL is excreted predominantly by the kidneys. Preexistent renal pathology or impairment of renal function may be expected to result in prolonged duration of anesthesia. TELAZOL should not be used in dogs and cats with severe cardiac or pulmonary dysfunction. Because the teratogenic potential of TELAZOL is unknown, it should not be used in pregnant bitches or queens at any stage of pregnancy. Also, a study has shown that TELAZOL crosses the placental barrier and produces respiratory depression in the newborn; therefore, its use for Cesarean section is contraindicated.

WARNINGS

FOR USE IN DOGS AND CATS ONLY.

When using TELAZOL for induction of anesthesia, patients should be continuously monitored. Facilities for the maintenance of a patent airway, artificial ventilation and oxygen supplementation should be available.
Pulmonary edema has been reported to occur in cats with the use of TELAZOL. Signs and symptoms include dyspnea, lethargy, anorexia and abnormal behavior. Deaths have been reported occasionally in severely affected individuals. Cats should be observed closely for any signs and symptoms which may suggest pulmonary edema so that appropriate therapy may be instituted.
The principal route of excretion of both components in the cat is the urine; therefore, TELAZOL is not recommended for use in cats suffering from renal insufficiency.
Balance studies in dogs indicated extensive biotransformation of both components with less than 4% of the dose excreted unchanged in the urine.
TELAZOL is excreted predominantly by the kidneys. Preexistent renal pathology or impairment of renal function may be expected to result in prolonged duration of anesthesia.
Phenothiazine-derivative drugs should not be used with TELAZOL at dosages indicated for intramuscular (IM) injection because the combination produces respiratory and myocardial depression, hypotension and hypothermia.
The safe use of TELAZOL in pregnant animals or on reproduction has not been established.
TELAZOL crosses the placental barrier and causes respiratory depression in the neonate.

PRECAUTIONS

The dosage of TELAZOL should be reduced in geriatric dogs and cats, in animals in debilitated condition and in animals with impairment of renal function. Death has occurred in both cats and dogs following intramuscular TELAZOL administration. Preexisting pulmonary disease, renal disease (see Contraindications and Warnings) and shock were causally implicated at necropsy; however, death was drug attributable in at least one dog (of 1072) and one cat (of 1095).
Intravenous TELAZOL has been demonstrated to be safe in a field study in dogs when used in conjunction with phenothiazine-derivative drugs

(acepromazine) administered at dosages from 0.04-0.06 mg/kg IM.
Cats and smaller dogs with small body masses in relation to large body surfaces should be protected from heat loss during TELAZOL anesthesia. Body temperature should be monitored, and supplemental heat may be required to control hypothermia. As with other anesthetics, it is prudent to provide for hemostasis during any surgical procedure.
During TELAZOL anesthesia, athetoid movement may occur. This athetosis should not be mistaken for lack of anesthesia nor is it indicative of lack of analgesia. Do not give additional anesthesia in an attempt to abolish the athetoid movement. Efforts to eliminate athetoid movement with additional doses of TELAZOL can result in anesthetic overdosage.
TELAZOL does not abolish laryngeal, pharyngeal, pinnal, palpebral, and pedal reflexes, and may not be adequate as the sole anesthetic for surgical procedures in these areas. Endotracheal tubes are not well tolerated in connection with TELAZOL anesthesia in the cat and their use may result in impaired respiration. After removal of the tube, normal respiration should resume.
The stimulation of surgical procedures aids in maintaining adequate ventilation. The anesthetized patient must be monitored throughout the procedure, and if cardiopulmonary problems do occur, measures must be taken to assure that alveolar ventilation and cardiovascular functions are maintained.
The eyes normally remain open with the pupils dilated. The use of a bland ophthalmic ointment is advisable to protect the corneas from desiccation.
The concurrent use of chloramphenicol will prolong the duration of anesthesia in cats.
Copious salivation may occur during TELAZOL anesthesia. Ptyalism may be controlled in dogs and cats by administering atropine sulfate, USP, 0.02 mg/lb (0.04 mg/kg) body weight (IV, IM, or SC) as concurrent medication. Exaggerated swallowing, reflex action and accumulation of saliva may give rise to vomiting and retching.

ADVERSE REACTIONS

For Restraint and Minor Procedures of Short Duration Requiring Mild to Moderate

Analgesia
Respiratory depression may occur following administration of high doses of TELAZOL. If at any time respiration becomes excessively depressed and the animal becomes cyanotic, resuscitative measures should be instituted promptly. Adequate pulmonary ventilation using either oxygen or room air is recommended as a resuscitative measure. Adverse reactions reported include emesis during emergence, excessive salivation, transient apnea, vocalization, erratic recovery and prolonged recovery, excessive tracheal and bronchial secretions when atropine sulfate, was not given before anesthesia, involuntary muscular twitching, hypertonicity, cyanosis, cardiac arrest, pulmonary edema and muscle rigidity during surgical procedures. Central nervous system stimulation and convulsions have also been reported. Tachycardia frequently occurs, particularly in the dog. This rise in heart rate usually lasts about 30 minutes. Either hypertension or hypotension may also occur. Insufficient anesthesia has been reported in dogs. Death has been reported in dogs and cats following TELAZOL administration.

Intravenous Induction of Anesthesia followed by Maintenance with Inhalant Anesthesia in Dogs
In a field study to assess the effectiveness and safety of TELAZOL administered intravenously at 1-2 mg/lb (2.2-4.4 mg/kg) for the induction of anesthesia followed by maintenance with inhalant anesthesia in dogs, 144 dogs were intravenously administered TELAZOL (See Effectiveness). Sixteen adverse reactions occurred during the study: nystagmus (5), emesis (4), diarrhea (2), and one occurrence each of hypersalivation, urticarial, anorexia, hyperthermia, and lethargy. All adverse reactions resolved by the end of the study. Physiologic abnormalities related to general anesthesia were transient and not severe. Post-induction apnea (time from induction to first inspiration ≥30 seconds) was observed in 49.3% of dogs across all treatment groups with a mean duration of one minute. The highest overall frequency and duration of post-induction apnea was in the alpha2-agonist + opioid groups. Overall, 36 dogs received assisted ventilation. Assisted ventilation was needed most frequently early in the procedure (at procedure start, possibly after an apneic period) then decreased in frequency as the procedure continued.

Sixteen dogs experienced oxygen saturation (SpO2) ≤90 mmHg: 7 in the alpha2-agonist + opioid groups, 6 in the phenothiazine + opioid groups, and 3 in the opioid alone groups. Twenty-five dogs had a temperature ≥103°F during the study, with 12 of these occurring prior to preanesthetic administration only. Of the remaining 13 dogs, 7 were in the alpha2-agonist + opioid groups, 5 were in the opioid alone groups, and 1 in the phenothiazine + opioid groups. One dog was reported with hyperthermia as an adverse reaction in the alpha2-agonist + opioid treatment groups. The dog became excitable during recovery and its temperature elevated to 105.7°F. Hyperthermia resolved with treatment of IV fluids and cooling.

Twenty-seven dogs experienced temperatures ≤96°F at one or more timepoints. Most dogs received supplemental heat during surgery. Fifty-nine dogs had mean blood pressure (BP) values ≤60 mmHg. These values are spread among all treatment groups. No dogs were reported with adverse reactions due to hypotension or hypertension in any dose groups. Elevated or low BP values were transient. Ventricular premature depolarizations were noted in 3 dogs in the alpha2-agonist + opioid group. This transient rhythm disturbance is not uncommon in dogs receiving alpha2-agonists or inhalant anesthetics. One dog in the phenothiazine + opioid group showed transient ST depression that could have been due to cardiac hypoxia. All dogs recovered normally.
For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Zoetis Inc. at 1-888-963-8471. Additional information can be found at www.Zoetis.US.com.
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

CLINICAL PHARMACOLOGY

Mechanism of Action

TELAZOL is a rapid-acting anesthetic combination of tiletamine hydrochloride and zolazepam hydrochloride. Tiletamine hydrochloride is a

dissociative anesthetic agent whose pharmacologic action is characterized by profound analgesia, normal pharyngeal-laryngeal reflexes and cataleptoid anesthesia. The anesthetic state produced does not fit into the conventional classification of stages of anesthesia, but instead TELAZOL produces a state of unconsciousness which has been termed “dissociative’’ anesthesia in that it appears to selectively interrupt association pathways to the brain before producing somesthetic sensory blockade.

Cranial nerve and spinal reflexes remain active; however, these reflexes must not be confused with inadequate anesthesia. Analgesia results from apparent selective interruption of sensory inputs to the brain and usually persists after the anesthetic effect has subsided.

Protective reflexes, such as coughing and swallowing, are maintained under tiletamine anesthesia. Other reflexes, e.g., corneal, pedal, are maintained during tiletamine anesthesia, and should not be used as criteria for judging depth of anesthesia. The eyes normally remain open with the pupil dilated. It is suggested that a bland ophthalmic ointment be applied to the cornea if anesthesia is to be prolonged.

Used alone, tiletamine hydrochloride does not provide adequate muscle relaxation for abdominal surgical procedures. When combined with zolazepam hydrochloride, good muscle relaxation is generally attained during the phase of deep surgical anesthesia.

Pharmacokinetics

The pharmacokinetics of TELAZOL injectable solution was evaluated in 12 healthy adult Beagle dogs, following a single intravenous (IV) administration of 2.2 mg/kg bodyweight, which is equivalent to 1.1 mg/kg for both tiletamine hydrochloride and zolazepam hydrochloride. After administration of 2.2 mg/kg TELAZOL IV, the initial mean concentration of tiletamine (C0) was 1018 ng/mL, the systemic clearance (CL) was 6223 mL/kg/h, the area under the curve to the last measured concentration (AUC 0-last) was 178 ng*hr/mL, and steady state volume of distribution (Vss) was 3250 mL/kg. The mean elimination half-life of tiletamine was 0.87 hours. For zolazepam, the mean C0 was 2594 ng/mL, CL was 1993 mL/kg/h and Vss was 604 mL/kg. The mean

elimination half-life of zolazepam was 0.41 hours. The mean C0 and AUC0-t(last) were approximately 2.5 and 3 times, respectively, greater for zolazepam than for tiletamine. However, the mean half-life (T1/2) of tiletamine was approximately 2.5 times longer than for zolazepam, resulting in quantifiable plasma concentrations up to 2 hours longer. Pretreatment with an alpha-2 agonist or phenothiazine followed by inhalant isoflurane has been shown to increase in the initial concentration of both tiletamine and zolazepam.

EFFECTIVENESS

Dogs

Preanesthesia

In a field study conducted at 6 veterinary hospitals, 144 dogs of various breeds, ranging in age from 4 months to 14 years (mean age 5 years) and body weights from 1.2- 85.5 kg, were enrolled for completion of a veterinary procedure requiring anesthesia. Dogs were preanesthetized with a phenothiazine + opioid, an opioid alone, or an alpha2-agonist + opioid at the study Investigator's discretion based on individual patient needs. Approximately 20 minutes later, dogs were intravenously administered TELAZOL at 1-2 mg/lb (2.2-4.4 mg/kg) 'to effect' of anesthesia and were intubated. After induction, dogs received either isoflurane or sevoflurane for anesthetic maintenance for at least 30 minutes. Procedures conducted included dental prophylaxis with or without extractions (64), ovariohysterectomy (31), castration (18), and mass removal (14). Upon completion of the procedure, dogs were monitored in recovery for 4 hours, then followed at home for 2-4 days, monitoring for the presence of abnormal clinical signs.

Of 144 dogs enrolled in the study, 142 (98.6%) were successfully intubated after intravenous administration of TELAZOL at a mean dosage of 1.2 mg/lb (2.7 mg/kg). The mean dosage range was lowest in the alpha2-agonist + opioid preanesthetic treatment group (0.9 mg/lb; 2 mg/kg) and highest in the opioid alone preanesthetic group (1.8 mg/lb; 3.9 mg/kg).

Overall induction quality evaluated on a scale of acceptable, intermediate, or unacceptable was acceptable in 131/142 (91.6%) dogs and intermediate in 12/143(8.4%) dogs. On a scale of

good, fair, or poor, study participants rated the quality of recovery from anesthesia as good in 75% of dogs (118/144) and fair in 18.1% (26/144). In an overall assessment of anesthesia, considering induction, maintenance, and recovery, was scored as excellent or good in 128/144 (88.9%) of dogs. Three dogs (2.1%) were rated with an overall assessment of anesthesia as poor, and for these dogs, recovery was also rated poor. Physiologic measurements of heart rate, respiratory rate, body temperature, oxygen saturation, and blood pressure during anesthetic induction, maintenance, and recovery showed that the administration of TELAZOL did not severely impact these variables. A variety of concomitant treatments were used during the study including intravenous fluid solutions, non-steroidal anti-inflammatory medications, antimicrobials, and antiparasitics that were consistent with routine canine practice.

ANIMAL SAFETY

TELAZOL has a wider margin of safety in cats than in dogs. Dogs have survived repeated IM dosage regimens of 13.6 mg/lb (30 mg/kg) (maximum safe dose) for eight successive days. This is approximately two times the maximum recommended therapeutic dose. Cats have survived IM dosage regimens of up to 32.7 mg/lb (72 mg/kg) (maximum safe dose) on alternate days for seven episodes. This is 4.6 times the maximum recommended therapeutic dose for cats. However, these reports should not obviate prudent anesthetic practices. Some degree of tolerance has been reported. This tolerance appears to be species-variable.

Cats

In cats, the duration of effect of zolazepam exceeds that of tiletamine so that as the animal recovers there is a greater degree of tranquilization than anesthetization. There is a slight lowering of blood pressure during the first hour after injection. Heart rate and electrocardiogram readings are unaffected by TELAZOL (tiletamine and zolazepam for injection). Arterial pO2 levels are decreased three minutes after injection but usually return to normal within 15 to 35 minutes.

Dogs
In dogs, the duration of effect of tiletamine exceeds that of zolazepam so there is a lesser degree of tranquilization than anesthetization in this species. The total effect of TELAZOL in dogs is of shorter duration than in cats.
Following administration of TELAZOL in dogs, a marked, persistent tachycardia occurs within two minutes following either 4.5 or 9 mg/lb (10 or 20 mg/kg) TELAZOL intramuscularly. Stroke volume decreases proportionately to the increased rate at the 4.5 mg/lb (10 mg/kg) dose, with little change in net cardiac output. There is an initial increase in systolic blood pressure, with a slight drop in pressure within five minutes. The systolic blood pressure remains at this decreased level throughout the duration of the anesthetic effect. Diastolic pressure increases throughout this same period. Following a 9 mg/lb (20 mg/kg) dose of TELAZOL in dogs, the relationship between stroke volume and heart rate is disproportionate, with a resultant substantial decrease in cardiac output. Contractility and mean blood pressure are decreased, indicating direct myocardial depression. Ventricular function is adequate. During surgical manipulations, tachycardia and hypertension may be observed, and may be brought on by sympathetic reaction to painful stimuli. Epinephrine is markedly less arrhythmogenic in animals under TELAZOL anesthesia than in those under halothane anesthesia. During TELAZOL anesthesia, the assurance of a patent airway is greatly enhanced by virtue of maintaining pharyngeal-laryngeal reflexes. During the first 15 minutes after intramuscular administration of 9 mg/lb (20 mg/kg) of TELAZOL, the respiratory rate is doubled while the tidal volume is decreased to less than one-half of control values. Arterial pO2 levels also decrease. This may be evidenced by hypoxemia and cyanosis. The pulmonary function usually returns to normal within 35 minutes after the administration of TELAZOL.

Preanesthetic Compatibility Study in Dogs
Six healthy Beagle dogs (3 males and 3 females), at least 8 months of age, ranging in body weight between 5.6 and 9.4 kg, were fitted with a telemetry device that captured systemic arterial blood pressures, electrocardiogram, and body temperature. Each dog received a total of 6 treatments with at least a 7-day washout between

periods. During each period, dogs received 1 of the following 6 preanesthetics prior to the TELAZOL administration: placebo (0.9% saline), acepromazine low dose (0.1 mg/kg body weight [BW]), acepromazine high dose (1.1 mg/kg BW), dexmedetomidine low dose (125 mcg/m2 body surface area [BSA]), dexmedetomidine high dose (375 mcg/m2 BSA), or butorphanol (0.4 mg/kg BW). Blood samples were collected at intubation, end of isoflurane administration, and after anesthesia when the dogs were able to walk. Plasma concentrations of tiletamine and zolazepam were measured using a validated method. Preanesthetic treatment with high dose acepromazine and both high and low doses of dexmedetomidine resulted in substantial increases in plasma concentrations of tiletamine and zolazepam at intubation. The increase in the tiletamine plasma concentrations was approximately 2X higher for the high dose of acepromazine and 2.7 to 4.5X higher for the low and high doses of dexmedetomidine, respectively, compared to saline. The increase in zolazepam plasma concentrations was 1.5X higher for the high dose acepromazine, and 1.8 to 2.8X higher for the low and high doses of dexmedetomidine, respectively, compared to saline.

No information on the dose-sparing of TELAZOL was obtained during the study because the dogs were given the full initial half-dose (2.2 mg/kg) and not actually administered TELAZOL ‘to effect’. The average total dose of test article administered to the dogs was 2.6 mg/kg for the saline group and 2.2 mg/kg for the other treatment groups. One dog (saline group) required more than the initial 2.2 mg/kg bolus to achieve intubation at the first attempt.

Without preanesthesia (saline group), dogs retained a strong cough reflex, chewing motions, tachycardia and increased muscle tone during intubation. With preanesthesia, half of the dogs in the high dose dexmedetomidine group had no laryngeal reflex response to intubation and all experienced post-intubation apnea. The postintubation apnea suggests that the 2.2 mg/kg dose of TELAZOL was higher than necessary in some groups.

All dogs in all treatment groups achieved successful anesthetic plane following TELAZOL administration and were intubated and induced to isoflurane anesthesia uneventfully. The quality of intubation,

and occurrence and severity of adverse reactions (e.g., apnea and bradypnea) following TELAZOL administration and intubation revealed differences among preanesthetic treatment groups. The cardiovascular and respiratory changes observed were typical of each preanesthetic medication used in combination with TELAZOL. Acepromazine and isoflurane administration decreased arterial blood pressure. Dexmedetomidine decreased heart rate. Intubation transiently increased heart rate and/or blood pressure (sympathetic stimulations). Mild to severe respiratory depression was observed after TELAZOL administration and each preanesthetic agent. Adverse reactions were manageable with appropriate care.

STORAGE CONDITIONS

Store at controlled room temperature 20° to 25°C (68° to 77°F). Discard unused solution after 7 days when stored at room temperature or after 56 days when kept refrigerated. Only use clear solution. Color of solution may vary from colorless to light amber.

HOW SUPPLIED

TELAZOL (tiletamine and zolazepam for injection) is available in individual vials of 5 mL solution when reconstituted. The addition of 5 mL diluent produces a solution containing the equivalent of 50 mg tiletamine base, 50 mg zolazepam base and 57.7 mg mannitol per milliliter.

10 mL vial -100 mg/mL total (equivalent to 50 mg/mL tiletamine and 50 mg/mL zolazepam) when reconstituted

Approved by FDA under NADA # 106-111

zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Revised: September 2022

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PRINCIPAL DISPLAY PANEL - 5 mL Bottle Label

TELAZOL

tiletamine hydrochloride and zolazepam hydrochloride injection, powder, for solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-9050
Route of Administration	INTRAMUSCULAR	**DEA Schedule**	CIII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TILETAMINE HYDROCHLORIDE (UNII: 99TAQ2QWJI) (TILETAMINE - UNII:2YFC543249)	TILETAMINE	50 mg in 1 mL
ZOLAZEPAM HYDROCHLORIDE (UNII: 45SJ093Q1N) (ZOLAZEPAM - UNII:G1R474U58U)	ZOLAZEPAM	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	57.7 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54771-9050-1	1 in 1 CARTON		
1		5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA106111	04/09/1982	

Labeler - Zoetis Inc. (828851555)

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