Zoletil™ for Injection
(tiletamine and zolazepam for injection)

C III

100 mg/mL total
(equivalent to 50 mg/mL tiletamine and 50 mg/mL zolazepam)

These highlights do not include all the information needed to use ZOLETIL™ for Injection (tiletamine and zolazepam for injection) safely and effectively. See full prescribing information.

Zoletil for Injection is for intramuscular and intravenous injection in dogs and intramuscular injection only in cats.

INDICATIONS

Dogs: Zoletil for Injection 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.) Zoletil for Injection administered intravenously is indicated in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

Cats: Zoletil for Injection 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 section in full prescribing information)

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) Zoletil for Injection is recommended for diagnostic purposes; 4.5 to 6 mg/lb (9.9 to 13.2 mg/kg) for minor procedures of short duration. When supplemental doses of Zoletil for Injection 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 section in full prescribing information.)

Intravenous (IV) For Induction of Anesthesia Followed by Maintenance with an Inhalant Anesthetic: In dogs, for induction of anesthesia, administer Zoletil for Injection intravenously at 1-2 mg/lb (2.2-4.4 mg/kg) body weight to effect. Zoletil for Injection 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 Zoletil for Injection may be administered; the total dose should not exceed 2 mg/lb (4.4 mg/kg) body weight.

Cats: In healthy cats, an initial Zoletil for Injection 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 ovariohysterectomy and onychectomy. When supplemental doses of Zoletil for Injection 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 section in full prescribing information)

CONTRAINDICATIONS

The use of Zoletil for Injection is contraindicated in dogs and cats with pancreatic disease. Zoletil for Injection should not be used in dogs and cats with severe cardiac or pulmonary dysfunction. Because the teratogenic potential of Zoletil for Injection is unknown, it should not be used in pregnant bitches or queens at any stage of pregnancy. Also, a study has shown that tiletamine and zolazepam for injection 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 Zoletil for Injection 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 tiletamine and zolazepam for injection. 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, Zoletil for Injection 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. Zoletil for Injection 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 Zoletil for Injection at dosages indicated for intramuscular (IM) injection because the combination produces respiratory and myocardial depression, hypotension and hypothermia. The safe use of Zoletil for Injection in pregnant animals or on reproduction has not been established. Zoletil for Injection crosses the placental barrier and causes respiratory depression in the neonate.

PRECAUTIONS

The dosage of Zoletil for Injection 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 tiletamine and zolazepam for injection 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 tiletamine and zolazepam for injection 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 Zoletil for Injection 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 Zoletil for Injection 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 Zoletil for Injection can result in anesthetic overdosage. Zoletil for Injection 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 Zoletil for Injection 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 Zoletil for Injection 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 Zoletil for Injection. 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 tiletamine and zolazepam for injection administration.

Intravenous Induction of Anesthesia followed by Maintenance with Inhalant Anesthesia in Dogs: In a field study to assess the effectiveness and safety of tiletamine and zolazepam for injection 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 tiletamine and zolazepam for injection (See Effectiveness in full prescribing information). Sixteen adverse reactions occurred during the study: nystagmus (5), emesis (4), diarrhea (2), and one occurrence each of hypersalivation, urticaria, 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 $alpha_2$-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 (SpO_2) ≤90 mmHg: 7 in the $alpha_2$-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 $alpha_2$-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 $alpha_2$-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 $alpha_2$-agonist + opioid group. This transient rhythm disturbance is not uncommon in dogs receiving $alpha_2$-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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc. at 1-800-338-3659 or vet-us.virbac.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

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