

Zoletil

INJECTABLE ANAESTHETIC

COMPOSITION

Each freeze-dried vial contains

ZOLETIL 100 Injectable Anaesthetic:

Tiletamine (as hydrochloride).....250 mg

Zolazepam (as hydrochloride).....250 mg

DESCRIPTION

ZOLETIL is a white to slightly yellow compact mass and a solvent for reconstitution.

PHARMACODYNAMICS

The combined drugs of ZOLETIL have a complementary mode of action. Tiletamine is a dissociative anaesthetic agent which is pharmacologically similar to Ketamine. Zolazepam, on the other hand, is a benzodiazepine, pharmacologically similar to diazepam. It is a sedative, an anxiolytic and a muscle relaxant. Zolazepam enhances the Tiletamine depression of the central nervous system. It also prevents the seizures due to Tiletamine and improves both muscle relaxation and emergence from anaesthesia.

ZOLETIL produces an anaesthetic effect which does not correspond to any conventional anaesthetic state. It produces a state of unconsciousness that has been referred to as dissociative because it appears to selectively interrupt association pathways to the brain before provoking anaesthetic sensory blockage. Analgesia results from the apparent selective interruption of sensory inputs to the brain.

Depending of the animal species, analgesia persists after the anaesthetic effect has subsided. In a great majority of the animals and unless the product is used at extremely high doses, pharyngeal and laryngeal reflexes remain intact. Cranial nerves and spinal reflexes remain intact. Consequently, the animal's eyes remain open and the animal can swallow, move its tongue, chew, blink its eyelids and move its limbs during the anaesthesia. The fact that all of these reflexes persist is not an indication that the anaesthesia is inadequate.

The actions of ZOLETIL can be summarised as follows :

Catalepsy :

- rapid, without agitation, followed by muscular relaxation.

Analgesia :

- immediate superficial analgesia

- moderate visceral analgesia

Surgical anaesthesia :

- with muscular relaxation

- persistence of laryngeal, pharyngeal and palpebral reflexes

- no depression of respiratory centre, possibility of salivation

PHARMACOKINETICS

Half-life of Tiletamine elimination is 75 minutes in dogs & 150 minutes in cat. Half-life for Zolazepam is 60minutes in dogs & 270 minutes in cats. Zoletil has no hepatic toxicity. Moreover, it does not modify the metabolism.

INDICATION

General anaesthesia for dogs and cats.

RECOMMENDED DOSAGE

Dogs: 0.1 mg per kg of atropine sulfate (subcutaneously) 15 minutes prior to the injection,

Cats: 0.05 mg per kg of atropine sulfate (subcutaneously) 15 minutes prior to injection.

Dosage

Reconstitute extemporaneously solution with all of the solvent provided. The dose is expressed as mg total product, whereby the product is reconstituted to a concentration of 100 mg/ml and contains 50mg per ml tiletamine and 50mg per ml zolazepam.

Dosage when the product is administered intramuscularly (loss reflex up in 3-6 minutes)

dogs:

- Examinations and procedures very painful: 7-10 mg per kg

- Minor operations, anesthesia of short duration: 10 to 15 mg per kg

- Major and painful procedures: 15-25 mg per kg.

cats:

- Examinations and procedures very painful: 10 mg per kg

- Major orthopedic operations: 15 mg per kg.

Dosage when the product is administered intravenously (loss reflex up in less than a minute):

dogs:

- Examinations and procedures very painful: 5 mg per kg

- Minor operations, short-term anesthesia, 7.5 mg per kg

- Major and painful procedures: 10 mg per kg.
- cats:
- Examinations and procedures very painful: 5 mg per kg
- Major orthopedic operations: 7.5 mg per kg.

The reinjection intravenous be used, if necessary, to 1/2 to 1/3 of the initial dose. Dosages are given by species, assume typical interventions; they must be qualified at the discretion of the practitioner according to the subject's condition (age, obesity, severe organic impairment, shock, late pregnancy, debilitating diseases).

Duration of anesthesia: 20-60 minutes depending on the dose.

Alarm clock: Analgesia persists longer than surgical anesthesia. The return to normal is gradual, rapid (2-6 hours on average), quiet (avoid excessive noise and lights). Recovery may be delayed by an overdose, in obese animals, elderly or debilitated.

MODE OF ADMINISTRATION

Intravenously or intramuscularly.

CONTRAINDICATIONS

- Severe cardiac or respiratory deficiencies
- Pancreatic deficiency
- Animals under treatment by systemic organophosphorous of carbamates
- Severe hypertension

WARNINGS/PRECAUTIONS

- For animal use only
- Food restriction of 12 hours prior anesthesia is recommended.
- Insure recovery in a quiet and dark place
- Protect anaesthetized animals from excessive heat loss.

INTERACTION WITH OTHER DRUGS

Do not use in conjunction with :

- Phenothiazines (acepromazine, chlorpromazine) because of risk of cardiac and respiratory depression and hypothermia
- Chloramphenicol because of the induced decrease in the elimination rate of the anaesthetic

PREGNANCY & LACTATION

Do not use in pregnant and lactating animals.

SIDE EFFECTS

In anaesthetized animals, neurological disorders (prostration, convulsions, coma, ..), or not associated with cardiorespiratory disorders (dyspnea, tachypnea, slow breathing, tachycardia, cyanosis, ...) and systemic disorders (hypothermia, hyperthermia, pupillary disorder, excessive salivation, ...) have been observed in very rare cases, mainly during the recovery phase in dogs and during surgery and during the recovery phase in the cat.

OVERDOSE & TREATMENT

The lethal dose in cats and dogs is about 100 mg per kg intramuscularly, i.e. 5 to 10 times the anaesthetic dose. In case of overdose and in obese or older animals, recovery may be slower. There is no specific antidote for tiletamine. Treatment is symptomatic.

INCOMPATIBILITIES : See Interactions with other drugs.

STORAGE : Store at room temperature up to 30°C, protect from excessive heat.

SHELF-LIFE

ZOLETIL is stable at least 2 years under freeze-dried form.

Shelf life of solvent (water for injection) is 24 months, when stored in the retailing package, at room temperature.

After reconstitution, ZOLETIL must be used within 48 hours if kept at 20°C or within 8 days at 4°C.

PRESENTATIONS

ZOLETIL 100: box of 2 vials (freeze-dried 990mg + 5ml solvent)

MANUFACTURER: Virbac Laboratories -1 ere avenue, 2065 M L.I.D., 06516 Carros, France

PRODUCT HOLDER: Pet Arcade Sdn Bhd, 94 Lorong Maarof, Bangsar Park, 59000 Kuala Lumpur.

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