

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetalar V 100 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Ketamine Hydrochloride 115.32 mg

(equivalent to Ketamine base) 100 mg

Excipients

Benzethonium Chloride Ph.Eur. 0.1 mg

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Vetalar alone - cats, sub-human primates

Vetalar/xylazine - cats, dogs and horses

Vetalar/medetomidine - cats and dogs

Vetalar/detomidine - horses

Vetalar/romifidine - horses

4.2 Indications for use, specifying the target species

As an anaesthetic agent. Specific indications include:-

Cat - Vetalar alone: Handling of fractious animals, wound repair, lancing abscesses, radiography and other minor and brief surgical procedures where muscle relaxation is not required.

Cat - Vetalar/xylazine: Spaying, castration, laparotomy, wound treatment, radiography, fracture repair, etc.

Cat - Vetalar/medetomidine: Spaying, castration, laparotomy, wound treatment, radiography, fracture repair, etc.

Dog - Vetalar/xylazine: To induce and maintain surgical anaesthesia in the dog. Short, seizure like movements can occasionally occur during anaesthesia, therefore, this technique is not recommended for delicate surgical procedures, e.g., delicate orthopaedic or eye surgery.

Dog - Vetalar/medetomidine: To induce and maintain surgical anaesthesia in the dog. Short, seizure like movements can occasionally occur during anaesthesia, therefore, this technique is not recommended for delicate surgical procedures, e.g., delicate orthopaedic or eye surgery.

Horse - Vetalar/xylazine: Castration, wound repair, radiography, induction agent for halothane and oxygen anaesthesia.

Horse - Vetalar/detomidine: For short duration surgical anaesthesia to carry out surgical procedures such as castration.

Horse - Vetalar/romifidine: Castration, wound repair, radiography, induction agent for halothane and oxygen anaesthesia.

Sub-human primates - Vetalar alone: Sedation for clinical examinations, blood sampling, etc. Light surgical anaesthesia for minor procedures.

4.3 Contraindications

General - If using Vetalar in conjunction with xylazine, medetomidine, detomidine, atipamezole or romifidine, reference should be made to the contra-indications and warnings specific to these products. For example xylazine and detomidine should not be used in late stages of pregnancy. Medetomidine must not be used in pregnant dogs or cats.

Other general contra-indications to the use of Vetalar are:

Vetalar is contra-indicated in patients with pre-existent hepatic or renal pathology. Caution on the use of Vetalar is required when pulmonary disease is present or suspected.

Species specific contra-indications to the use of Vetalar are:

Dogs - Due to risk of occasional short seizure-like movements, this anaesthetic technique is not recommended for use in delicate surgical procedures.

Atipamezole should not be used to speed up recovery in dogs.

Horses - Vetalar must not be used as the sole anaesthetic agent in horses.

4.4 Special warnings for each target species

Cats - Cats, after administration of Vetalar, should not be stimulated by sound or handling during the recovery period. They should be kept at normal room temperature.

Dogs - In some dogs, especially excitable dogs, insufficient anaesthesia as indicated by poor muscle relaxation and occasionally short seizure-like movements may occur. Quiet handling before and after induction will help to minimise this effect.

Due to the risk of occasional short seizure-like movements, this anaesthetic technique is not recommended for use in delicate surgical procedures.

Atipamezole should not be used to speed up recovery in dogs.

Horses - Vetalar must not be used as the sole anaesthetic agent in horses. Excitable horses are sometimes poor subjects for anaesthesia. It is a prime requisite that the horse should be quietly and carefully handled during the administration of the anaesthetic agents so as to ensure the minimum amount of upset during the induction period.

If the horse fails to become sedated following the injection of either xylazine, detomidine or romifidine, then Vetalar should not be injected and the anaesthetic procedure should be abandoned.

4.5 Special precautions for use

Special precautions for use in animals

Vetalar is contra-indicated in patients with pre-existent hepatic or renal pathology. Caution on the use of Vetalar is required when pulmonary disease is present or suspected.

Care should be taken when using halothane/ketamine combinations since the half-life of ketamine is prolonged.

It is advisable that where general anaesthesia is induced, animals are previously starved for at least 12 hours.

A small proportion of animals have been reported to be unresponsive to ketamine as an anaesthetic agent at normal doses.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This is a potent drug - particular care should be taken to avoid accidental self administration.

Wash off splashes from skin and eyes immediately.

In the event of accidental self administration - seek urgent medical attention and show this label.

Advice to doctor : Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

4.6 Adverse reactions (frequency and seriousness)

With Vetalar anaesthesia the eyes normally remain open with the pupils dilated. The eyes should be protected by covering with a damp gauze swab or by application of a bland ophthalmic ointment.

4.7 Use during pregnancy, lactation or lay

Although the safety of ketamine has not been fully evaluated in pregnant and lactating animals, there is no evidence to suggest that its use in these animals produces harmful effects. See warnings/contra-indications for other products used in combination with Ketamine.

Due to the transfer of ketamine across the placental barrier, respiratory depression may result in newborn animals.

4.8 Interaction with other medicinal products and other forms of interaction

Experimental studies have shown that ketamine interacts with a number of substances acting in the nervous system and these interactions may have a marked effect on the quality and/or duration of anaesthesia. It is recommended that only the registered combinations are used and that the contra-indications and warnings associated with any other product substance used in combination with ketamine are fully considered before use.

4.9 Amounts to be administered and administration route

CAT - VETALAR

Dosage and administration Vetalar may be used by intravenous or subcutaneous injection, but intramuscular injection is the preferred recommended route. The dose is 11 - 33 mg ketamine/kg bodyweight depending on the degree of restraint or surgical interference that is intended.

Following intramuscular administration of recommended doses, cats become ataxic in about 5 minutes with anaesthesia usually lasting 30 - 45 minutes. Complete recovery usually occurs in 4 - 5 hours, but with higher doses recovery is more prolonged. The individual response to Vetalar is variable and depends upon the general condition and age of the subject.

Fasting prior to administration of Vetalar is not essential due to the maintenance of the pharyngeal-laryngeal reflexes. However, when preparing for elective surgery, it is advisable to withhold food for at least 6 hours prior to administration of Vetalar.

CAT - XYLAZINE/VETALAR

Dosage and administration Administer xylazine at a dosage of 1.1 mg/kg by intramuscular injection. This injection is followed immediately by an intramuscular injection of 0.04 mg/kg atropine sulphate and an intramuscular injection of Vetalar at a dosage of 22 mg ketamine per kg.

Due to low dose volumes, it is advisable to use an insulin type syringe to accurately measure dosages. Following this procedure the average time for onset of anaesthesia is 5 minutes. Surgical anaesthesia should be maintained for at least 30 minutes. If the cat is not starved prior to anaesthesia, then there should be an interval of 20 minutes between the xylazine and Vetalar injections. Vomiting will normally occur within 3 - 18 minutes of the xylazine injection in cats with a full stomach. Vomiting and aspiration are unlikely to be a problem in starved cats.

CAT - MEDETOMIDINE/VETALAR

Dosage and administration By intramuscular injection, administer medetomidine at a dosage of 80 µg/kg and Vetalar at a dosage of 5.0 to 7.5 mg ketamine per kg.

Due to low dose volumes, it is advisable to use an insulin type syringe to accurately measure dosages. Vetalar and medetomidine (in the form of Domitor) may be administered in the same syringe, however, to minimise the risk of cross contamination, the vials of Vetalar and medetomidine should have separate needles inserted for withdrawal. The average onset of anaesthesia is 3 - 4 minutes. Duration of surgical anaesthesia will vary between 30 - 60 minutes and is related to the dose of Vetalar used.

To speed recovery from anaesthesia (in cats only), atipamezole 5 mg/ml solution may be administered at a dose of 200 µg/kg. Thus in the cat the dose volume of atipamezole 5 mg/ml solution required is half that of the previously administered medetomidine 1 mg/ml solution.

DOG - XYLAZINE/VETALAR

Dosage and administration Administer xylazine by intramuscular injection at a dosage of 2 mg/kg. Atropine at recommended dose rates should be given to control salivation. In dogs weighing over 25 kg, the dose of xylazine should be reduced by one-third to 1.3 mg/kg.

After 10 minutes, administer Vetalar at a dosage of 10 mg ketamine per kg by intramuscular injection.

The dog should be kept quiet and unnecessary stimulation avoided during the induction period. Surgical anaesthesia is usually obtained within 10 minutes of the Vetalar injection and maintained for approximately 30 minutes.

DOG - MEDETOMIDINE/VETALAR

Dosage and administration By intramuscular injection, administer medetomidine at a dosage of 40 µg/kg and Vetalar at a dosage of 5.0 to 7.5 mg ketamine per kg.

Vetalar and medetomidine (in the form of Domitor) may be administered in the same syringe, however, to minimise the risk of cross contamination, the vials of Vetalar and medetomidine should have separate needles inserted for withdrawal. The duration of surgical anaesthesia varies between 30-50 minutes and is related to the dose of Vetalar used. Atropine is not normally required when using a Vetalar/medetomidine combination. Atipamezole should not be used to speed up recovery in dogs.

HORSE - XYLAZINE/VETALAR

Dosage and administration Xylazine should be administered by slow intravenous injection at a dosage of 1.1 mg/kg. The horse should appear sedated by 2 minutes post xylazine injection. Vetalar should then be administered at a dosage of 2.2 mg ketamine per kg as an intravenous bolus.

It is a prime requisite that the horse should be quietly and carefully handled during the administration of the anaesthetic agents so as to ensure the minimum amount of upset during the induction period. Onset of anaesthesia is gradual, the horse taking approximately 1 minute to become recumbent. In large fit horses, recumbency may take longer. Anaesthesia will continue to deepen for a further 1 - 2 minutes and during this time the horse should be left quietly.

Horses will regain sternal recumbency approximately 30 minutes post ketamine administration. Duration of surgical anaesthesia is variable lasting 10-30 minutes but usually less than 20 minutes.

Owing to the abrupt nature of the recovery, the intended procedure should be completed, if possible, within approximately 15 minutes.

For longer periods of anaesthesia, intubation and maintenance by inhalational, halothane and oxygen, anaesthesia should be used.

Should maintenance of surgical anaesthesia be required and facilities for gaseous anaesthesia are not available, the following procedure may be followed:-

Administer 0.55 mg/kg xylazine by intravenous injection followed immediately by 1.1 mg/kg ketamine (Vetalar) by intravenous injection. (These dose rates are half the original induction dosages). Anaesthesia should be maintained for approximately 10 - 15 minutes following top-up administration. More than one top-up dose can be given if anaesthesia needs to be prolonged for longer periods.

This method of prolonging anaesthesia is not recommended for routine maintenance of anaesthesia in which maintenance with gaseous anaesthesia would ordinarily be used.

HORSE - DETOMIDINE/VETALAR

Dosage and administration Administer detomidine at a dosage of 20 µg/kg by intravenous injection. Allow 5 minutes for the horse to become deeply sedated then administer Vetalar at a dosage of 2.2 mg ketamine per kg as an intravenous bolus.

Onset of anaesthesia is gradual, the horse taking approximately 1 minute to become recumbent. In large fit horses, recumbency may take up to 3 minutes.

Anaesthesia will continue to deepen for a further 1-2 minutes and during this time the horse should be left quietly. Horses regain sternal recumbency approximately 20 minutes post ketamine administration.

The duration of surgical anaesthesia is approximately 10 - 15 minutes and if for any reason it is necessary to prolong anaesthesia, thiopentone sodium can be administered intravenously in boluses of 1 - 2.0 mg/kg as required. Incremental doses totalling 5 mg/kg have been given. Total doses greater than this may reduce the quality of recovery.

Thiopentone can also be administered (as above regime) if sufficient depth of anaesthesia is not achieved.

The horse should be allowed to stand in its own time. The horse may be ataxic if it is encouraged to stand prematurely.

To facilitate handling and the administration of the induction agents, some horses have received acepromazine ACP by intramuscular injection at a dose rate of 0.03 mg/kg at least 45 minutes before induction of anaesthesia. (0.3 mls of 10 % ACP solution per 100 kg bodyweight).

HORSE - ROMIFIDINE/VETALAR

Dosage and administration Administer romifidine at a dosage of 100 µg/kg bodyweight. After 5 to 10 minutes, administer Vetalar at a dosage of 2.2 mg ketamine per kg as an intravenous bolus.

After induction, should deepening or maintenance of surgical anaesthesia be required and facilities for gaseous anaesthesia are not available either of the following two procedures may be followed:-

- 1) Administer romifidine, 25 µg/kg, (¼ original induction dose) intravenously followed immediately by Vetalar intravenously at a dosage of 1.1 mg ketamine/kg (½ original induction dose). This should be administered prior to commencement of surgical anaesthesia and/or when early signs of returning consciousness appear. Anaesthesia should be maintained for a further 10 - 15 minutes.
- 2) Administer thiopentone at a dosage of 2.5 mg/kg. This should be administered when signs of returning consciousness appear. Each repeat dose will provide approximately 10 minutes additional anaesthesia.

SUB-HUMAN PRIMATES - VETALAR

Dosage and administration By intramuscular injection.

Sedation 5 - 16 mg ketamine per kg bw (1 ml Vetalar per 20 kg bw, to 1 ml Vetalar per 6 kg bw).

Light anaesthesia 10 - 33 mg ketamine per kg bw (1 ml Vetalar per 10 kg bw, to 1 ml Vetalar per 3 kg bw). The dosage of Vetalar in sub-human primates is inversely proportional to weight in many species, i.e., as the animal's size increases the mg/kg dosage required decreases.

Temperament of the animal may also effect dosage.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdosage - Respiratory depression may occur following administration of high doses of Vetalar. If, at any time, respiration seems excessively depressed and the animal becomes cyanotic, resuscitative measures should be instituted promptly. Adequate pulmonary ventilation with either oxygen or room air is recommended as there is temporary cardiovascular stimulation. Cardiac stimulants should not be used.

4.11 Withdrawal Period(s)

Meat and offal: 28 days.

Vetalar is not for use in other food producing animals.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: General anesthetic; Ketamine

ATCvet code: QN01AX03.

5.1 Pharmacodynamic properties

Vetalar V is a solution containing 100 mg ketamine base per ml.

Ketamine is a rapidly acting non-barbiturate, non-narcotic, dissociative general anaesthetic. It can be used alone in cats and sub-human primates for restraint or as the sole anaesthetic agent in diagnostic or in minor and brief surgical procedures that do not require complete skeletal muscle relaxation. For surgical procedures requiring muscle relaxation, Vetalar V must be used in conjunction with alpha-adrenergic sedation i.e. in conjunction with

1. xylazine in cats, dogs and horses
2. medetomidine in cats and dogs
3. detomidine or romifidine in horses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzethonium Chloride.

Water.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except for use with the product Domitor.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

Protect from light.

6.5 Nature and composition of immediate packaging

Clear, colourless Type I glass vials containing 5, 10, 20 or 50 ml of colourless solution sealed with a red bromobutyl rubber stopper secured with a coloured aluminium collar – 5 ml silver, 10 ml gold, 20 ml & 50 ml red.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/114/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2010

10 DATE OF REVISION OF THE TEXT

April 2014