

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetalar V 100 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains ketamine hydrochloride (equivalent to 100 mg ketamine base) with 0.01% w/v benzethonium chloride as preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

20 ml

5. TARGET SPECIES

Cat, dog, horse and sub-human primates

6. INDICATION(S)

For use alone in cats and subhuman primates. In conjunction with xylazine in the cat, dog and horse. In conjunction with medetomidine in the cat and dog. In conjunction with detomidine or romifidine in the horse. In the cat, atipamezole may be used to speed recovery from anaesthesia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For full details on indications, dose, route and warnings, see package leaflet.

8. WITHDRAWAL PERIOD

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9. SPECIAL WARNING(S), IF NECESSARY

Following withdrawal of the first dose, use the product within 28 days. Vetalar should not be mixed with other products except Domitor™.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Protect form light

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]



POM-V

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4165

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS
{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetalar V 100 mg/ml Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains ketamine hydrochloride (equivalent to 100 mg ketamine base) with 0.01% w/v benzethonium chloride as preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

20 ml

4. ROUTE(S) OF ADMINISTRATION

For full details on indications, dose, route, warnings and disposal advice, see package leaflet.

5. WITHDRAWAL PERIOD

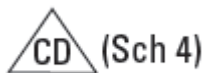
6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Expires end:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"



POM-V

Keep the vial in the outer carton. Protect from light.

Avoid the introduction of contamination during use. Following withdrawal of the first dose, use the product within 28 days.

Vetalar should not be mixed with other products except Domitor™.

Zoetis UK Limited

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Springfield Drive

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Surrey

KT22 7LP

Vm 42058/4165

To be supplied only on veterinary prescription. Keep out of the sight and reach of children.
For animal treatment only.

PACKAGE LEAFLET FOR: Vetalar V 100 mg/ml Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetalar V 100 mg/ml Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Presentation: Vetalar (Ketamine hydrochloride) is a colourless solution for injection containing 100 mg ketamine base per ml. Also contains 0.01% w/v Benzethonium chloride as preservative.

4. INDICATION(S)

Uses: Vetalar is a non-barbiturate, non-narcotic, parenteral anaesthetic. Vetalar can be used alone in cats and sub-human primates and produces an anaesthetic state characterised by profound analgesia, normal pharyngeal-laryngeal reflexes and normal skeletal tone. Vetalar may be used for restraint or as the sole anaesthetic agent in diagnostic or minor and brief surgical procedures that do not require complete skeletal muscle relaxation. For surgical procedures requiring muscle relaxation, Vetalar may be used in conjunction with xylazine in the cat, dog and horse, in conjunction with medetomidine in the cat and dog, and in conjunction with detomidine or romifidine in the horse.

5. CONTRAINDICATIONS

If using Vetalar in conjunction with xylazine, medetomidine or detomidine reference should be made to the contra-indications and warnings specific to these products in conjunction with the following contra-indications and warnings. For example, xylazine and detomidine should not be used in late stages of pregnancy. Medetomidine must not be used in pregnant dogs and cats. Vetalar is contra-indicated in patients with pre-existent hepatic or renal pathology.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Cats, dogs, horse and sub-human primates.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

CAT – Vetalar

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

Dosage and administration: For restraint, 11-22 mg/kg ketamine. For minor surgical procedures that do not require skeletal muscle relaxation, 22-33 mg/kg ketamine. The intramuscular route is normally recommended but Vetalar may be administered satisfactorily by the subcutaneous or intravenous routes at the same dosage.

Weight of cat (kg)	Restraint 11 mg/kg	Minor Surgery	
		22 mg/kg	33 mg/kg
1	0.11	0.22	0.33
2	0.22	0.44	0.66
3	0.33	0.66	0.99
4	0.44	0.88	1.32
5	0.55	1.10	1.65

Following intramuscular administration of recommended doses, cats become ataxic in about five 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 six hours prior to administration of Vetalar.

CAT – XYLAZINE/Vetalar

Indications: Spaying, castration, laparotomy, wound treatment, radiography, fracture repair etc.

Dosage and administration: To obtain satisfactory surgical anaesthesia, it is recommended that the following procedure is followed. Administer xylazine at a dose of 1.1 mg/kg by intramuscular injection. This injection is followed immediately by an intramuscular injection 0.04 mg/kg atropine sulphate, and an intramuscular injection of 22 mg/kg ketamine (Vetalar).

Weight of cat (kg)	Dose of xylazine 2% Solution (ml)	Dose of Vetalar (ml)
1	0.06	0.22
2	0.11	0.44
3	0.17	0.66
4	0.22	0.88
5	0.28	1.10

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

CAT – MEDETOMIDINE/Vetalar

Indications: Spaying, castration, laparotomy, wound treatment, radiography, fracture repair, etc.

Dosage and administration: To obtain satisfactory surgical anaesthesia, it is recommended that the following procedure is followed. Due to low dose volumes, it is advisable to use an insulin-type syringe to accurately measure dosages. Administer medetomidine at a dose rate of 80 µg/kg by intramuscular injection. This injection is followed immediately by the intramuscular injection of ketamine (Vetalar) at a dose rate of 5.0-7.5 mg ketamine/kg. Although ketamine hydrochloride and medetomidine may be administered concomitantly, only Vetalar and Domitor* injections may be combined and administered in the same syringe. To minimise the risk of cross contamination the vials of Vetalar and Domitor* 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 ketamine (Vetalar) used. To speed recovery from anaesthesia, atipamezole 5 mg/ml solution may be administered at a dose of 200 µg/kg. Thus in the cat, the dose of atipamezole 5 mg/ml solution required is half that of the previously administered medetomidine 1 mg/ml solution. Atropine is not normally necessary when using a Vetalar/medetomidine combination.

Weight of cat (kg)	Dose of medetomidine 1mg/ml solution (ml)	Dose of Vetalar 5.0 mg/kg (ml)	Dose of Vetalar 7.5 mg/kg (ml)
1	0.08	0.05	0.08
2	0.16	0.10	0.15
3	0.24	0.15	0.23
4	0.32	0.20	0.30
5	0.40	0.25	0.38

DOG – XYLAZINE/Vetalar

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

Dosage and administration:

Administer xylazine by intramuscular injection at a dose of 2 mg/kg bodyweight. Atropine should be given at this time to control salivation. In dogs weighing over 25 kg the dose of xylazine should be reduced by one-third to 1.3 mg/kg bodyweight. After ten minutes, administer ketamine (Vetalar) at a dosage of 10 mg/kg bodyweight by intramuscular injection.

Weight of dog (kg)	Dose of xylazine 2% Solution (ml)	Dose of Vetalar (ml)
5	0.5	0.5
10	1.0	1.0
15	1.5	1.5
20	2.0	2.0
25	2.5	2.5
30	2.0*	3.0
35	2.3*	3.5

*The dosage of xylazine in dogs weighing over 25 kg is reduced from 2.0 mg/kg to 1.3 mg/kg. The dog should be kept quiet and unnecessary stimulation avoided during the induction period. Surgical anaesthesia is usually obtained within ten minutes of the Vetalar injection and maintained for approximately 30 minutes. Anaesthesia may be prolonged by incremental intramuscular doses of ketamine (Vetalar) at half the original dose i.e 5 mg/kg bodyweight.

DOG – MEDETOMIDINE/Vetalar Indications: To induce and maintain surgical anaesthesia. Short seizure-like movements can occasionally occur during Vetalar / medetomidine anaesthesia, therefore, this anaesthetic technique is not

recommended for delicate surgical procedures e.g. delicate orthopaedic or eye surgery.

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.

Weight of dog (kg)	Dose of medetomidine 1mg/ml solution (ml)	Dose of Vetalar 5.0 mg/kg (ml)	Dose of Vetalar 7.5 mg/kg (ml)
5	0.2	0.25	0.38
10	0.4	0.50	0.75
15	0.6	0.75	1.13
20	0.8	1.00	1.50
25	1.0	1.25	1.88
30	1.2	1.50	2.25
35	1.4	1.75	2.63

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

HORSE – XYLAZINE/Vetalar

Indications: Castration, wound repair, radiography, induction agent for halothane and oxygen anaesthesia.

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.

Weight of horse (kg)	Dose of xylazine 2% Solution (ml)	Dose of xylazine 10% solution (ml)	Dose of Vetalar (ml)
100	5.5	1.1	2.2
200	11.0	2.2	4.4
300	16.5	3.3	6.6
400	22.0	4.4	8.8
500	27.5	5.5	11.0
600	33.0	6.6	13.2

For prolongation of anaesthesia xylazine and Vetalar may be administered at half the original induction dose. 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 anaesthesia and oxygen, 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 topup 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

Indications: For short duration general anaesthesia to carry out surgical procedures such as castration.

Dosage and administration: Vetalar must not be used as the sole anaesthetic agent in horses. It is important that, to obtain satisfactory surgical anaesthesia, the following procedure is followed. Administer detomidine at a dose rate of 20 µg/kg by intravenous injection. Allow five minutes for the horse to become deeply sedate then administer ketamine (Vetalar) at a dose rate of 2.2 mg/kg as an intravenous bolus.

Weight of horse (kg)	Dose of detomidine solution (ml)	Dose of Vetalar (ml)	2mg/kg dose of 5% thiopentone if required for supplementation of anaesthesia (ml)
100	0.20	2.2	4.0
200	0.40	4.4	8.0
300	0.60	6.6	12.0
400	0.80	8.8	16.0
500	1.00	11.0	20.0
600	1.20	13.2	24.0

Onset of anaesthesia is gradual, the horse taking approximately one minute to become recumbent. In large fit horses recumbency may take up to three 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 Vetalar injection. Duration of surgical anaesthesia is approximately 10-15 minutes. 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. Total doses of 5 mg/kg (five 1 mg/kg increments) have been given. Total doses greater than this may reduce the quality of recovery. Thiopentone can also be administered (as in the above regimen) 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 encouraged to stand prematurely. To facilitate handling and the administration of the induction agents, some horses have received acepromazine by intramuscular injection at a dose rate of 0.03 mg/kg at least 45 minutes before induction of anaesthesia.

HORSE – ROMIFIDINE/Vetalar

Indications: Castration, wound repair, radiography, induction agent for gaseous anaesthesia.

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 mg/kg, (1/4 original induction dose) intravenously followed immediately by Vetalar intravenously at a dosage of 1.1 mg ketamine/kg (1/2 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.

Weight of horse (kg)	Induction Doses	
	Dose of romifidine 10 mg/ml solution (mls)	Dose of Vetalar (mls)
100	1.0	2.2
200	2.0	4.4
300	3.0	6.6
400	4.0	8.8
500	5.0	11.0
600	6.0	13.2

Weight of horse (kg)	Prolongation doses Romifidine/Vetalar (if required)		Prolongation doses Thiopentone (if required)
	Dose of romifidine 10 mg/ml solution (mls)	Dose of Vetalar (mls)	5% thiopentone (mls)
100	0.25	1.1	5
200	0.50	2.2	10
300	0.75	3.3	15
400	1.00	4.4	20
500	1.25	5.5	25
600	1.50	6.6	30

SUB-HUMAN PRIMATES – Vetalar

Indications: Sedation for clinical examinations, blood sampling, etc light surgical anaesthesia for minor procedures.

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 the dosage.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from light. Vetalar must not be mixed with other products, with the exception of Domitor™. Following withdrawal of the first dose, use the product within 28 days. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded. Discard unused material.

12. SPECIAL WARNING(S)

Caution is required when pulmonary disease is present or suspected. 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. 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.

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 occasional 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. Atipamizole 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 detomidine, romifidine or xylazine, then Vetalar should not be injected and the anaesthetic procedure should be abandoned.

For animal treatment only.

Operator Warnings

1. This is a potent drug – particular care should be taken to avoid accidental self-injection.
2. Wash off splashes from skin and eyes immediately.
3. In the event of accidental self-injection – seek urgent medical attention and show this label.
4. Advice to doctor: Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

POM-V To be supplied only on veterinary prescription



Schedule 4, Part I

Package quantities

Available in 10 or 20 ml rubber capped multi-dose vials. Not all pack sizes may be marketed.

Further information

Treatment of overdose: 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.

Vm 42058/4165



Approved 06 November 2020