1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketavet 100 mg/ml
Solution for injection for Dogs, cats and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Ketamine hydrochloride: 115.36mg
(Equivalent to ketamine base) 100mg
Excipient(s):
Benzethonium chloride Ph. Eur: 0.10mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dog, cat, horse and sub-human primates.

4.2 Indications for use, specifying the target species

DOG
To induce anaesthesia in conjunction with medetomidine, butorphanol and xylazine.

CAT
As a sole agent for restraint and minor surgical procedures where muscle relaxation is not required. To induce anaesthesia in conjunction with acepromazine, butorphanol, xylazine and medetomidine. Endotracheal intubation can be achieved during anaesthesia with the product. Inhalation anaesthesia may be maintained by suitable combinations of methoxyflurane, halothane, nitrous oxide and oxygen.

HORSE
For the production of short-term anaesthesia in conjunction with detomidine, romifidine and xylazine, suitable for minor surgical interference's or for induction prior to inhalation anaesthesia. When romifidine or detomidine are used as the premedicant, anaesthesia may also be maintained with a 'top-up' combination of either romifidine and ketamine or detomidine and ketamine.

SUB-HUMAN PRIMATES
As a sole agent for restraint and minor surgical procedures where muscle relaxation is not required. Ketamine may also be used in combination with acepromazine.

4.3 Contraindications

General: When used in combination with other products, consult the contra-indications and warnings that appear on the relevant data sheets. For example, xylazine and detomidine must not be used in late stages of pregnancy and medetomidine must not be used in pregnant cats.

Do not use in animals with pre-existing hepatic or renal pathology. Caution on the use of ketamine is required when pulmonary disease is present or suspected.

Dogs: Do not use atipamezole to speed up recovery.

Horses: Do not use ketamine as a sole agent.

4.4 Special warnings for each target species

DOG
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

CAT
Ketamine may cause salivation in cats. To reduce salivation atropine premedication is recommended at 0.05mg/kg. Atropine is not normally necessary when using a medetomidine/ketamine combination.

Vomiting is unlikely to occur when the medicinal product is used alone; however cats should be starved for several hours prior to anaesthesia where possible.

Induction and recovery should be allowed to occur in quiet and calm surroundings.

HORSE
When using a total intravenous technique and for safe and effective use of a top-up regime, the use of an intravenous catheter is strongly advised.

Excitable horses are sometimes poor subjects for anaesthesia. To achieve the best results, it is important the horses are not stressed before the anaesthetic and that the whole procedure, from induction to recovery, should take place in quiet and calm surroundings. For horses that are stressed before the procedure, the use of 0.03mg/kg acepromazine 45 minutes prior to administration of either detomidine or romifidine facilitates handling and placement of an intravenous catheter.

If the horse fails to become sedated following the injection of xylazine, detomidine or romifidine, then ketamine should not be injected and the anaesthetic procedure should be abandoned. The situation should be assessed to establish why the horse failed to respond, and then the environment and/or the drugs should be adjusted as necessary, before trying again the following day.

During castration it has been noted that the use of 10mls lidocaine divided between the testicles eliminates the possible response to ligation of the testicular cord and minimises the number of top-ups required.

4.5 Special precautions for use

Special precautions for use in animals

It is generally accepted as good anaesthetic practice to starve animals for a period prior to anaesthesia where possible.

A small proportion of animals have been reported to be unresponsive to ketamine as an

anaesthetic agent at normal dosages.

Use of premedicants should be followed by a suitable reduction in dosage.
Care should be taken when using combinations of the veterinary medicinal product with halothane since the half-life of ketamine is prolonged.

For small volumes, use of either insulin syringes or 1ml graduated syringes is recommended to ensure accurate dosing.

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 injection/ self-administration. Preferably use a guarded needle until the moment of injection.
Wash off splashes from the skin and eyes immediately.

In the event of accidental self-administration - seek urgent medical attention and show this package leaflet to the doctor.

DO NOT DRIVE.

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

4..6 Adverse reactions (frequency and seriousness)

There may be some pain on intramuscular injection.

The most common adverse reactions are of the nervous system (salivation, myoclonia, hyperaesthesia, mydriasis):
Ketamine may cause salivation in cats. Atropine premedication (0.05mg/kg) may reduce this side effect.

Muscular twitching and mild tonic convulsions have been recorded in the cat at recommended dose rates. These subside spontaneously but may be prevented by use of acepromazine or xylazine premedication, or controlled by use of acepromazine or ultra short acting barbiturates in low doses.

In the cat and dog the eyes remain open and the pupils dilated. The eyes may be protected by covering with a damp gauze swab.

Respiratory depression (as evidenced by a decrease in respiratory rate) may occur. The degree of depression is dose dependent.

In some horses a mild, reversible heart block has been observed following premedication with detomidine.

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. When used in combination with other products, consult the contra-indications and warnings that appear on the relevant data sheets.

Due to 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

Care should be taken when using combinations of the veterinary medicinal product and halothane since the half-life of ketamine is prolonged.

4.9 Amounts to be administered and administration route

It should be noted that dosage and routes of administration vary widely between species.

DOG - XYLAZINE/KETAMINE

Dosage and administration: Administer xylazine at a dose rate of 1mg xylazine/kg by intramuscular injection. Immediately administer the product at a dose rate of 1.5ml/10kg bodyweight (equivalent to 15mg ketamine/kg) by intramuscular injection.

Effect: Dogs become recumbent in approximately 3 minutes and lose their pedal reflex in approximately 7 minutes. Duration of anaesthesia is approximately 24 minutes, the pedal reflex returning about 31 minutes following administration of the product.

Xylazine and Ketamine Canine Anaesthesia – (IM)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
*Xylazine (2% sol.) – mls:-	0.05	0.15	0.25	0.50	0.75	1.00	1.25	1.50	2.00
**Ketamine (100mg/ml) – mls:-	0.15	0.45	0.75	1.50	2.25	3.00	3.75	4.50	6.00

* Based on a dose rate of 1mg xylazine/kg bodyweight
** Based on a dose rate of 15mg ketamine/kg bodyweight

DOG - MEDETOMIDINE/KETAMINE

Dosage and administration: Administer medetomidine at a dose rate of 40µg medetomidine/kg and the product at a dose rate of 0.5-0.75ml/10kg bodyweight (equivalent to 5.0-7.5mg ketamine/kg), depending on duration of anaesthesia required, by intramuscular injection.

Effect: Loss of pedal reflex occurs approximately 11 minutes following injection at 5mg/kg and 7 minutes following injection at 7.5mg/kg. Duration of anaesthesia is approximately 30 and 50 minutes respectively.

Medetomidine and Ketamine Canine Anaesthesia – (IM)

Dosage chart for 5mg ketamine/kg (duration of anaesthesia approximately 30 minutes)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
*Medetomidine (1mg/ml) – mls:	0.04	0.12	0.20	0.40	0.60	0.80	1.00	1.20	1.60
**Ketamine (100mg/ml) – mls:-	0.05	0.15	0.25	0.50	0.75	1.00	1.25	1.50	2.00

* Based on a dose rate of 40µg medetomidine/kg bodyweight
** Based on a dose rate of 5mg ketamine/kg bodyweight

Medetomidine and Ketamine Canine Anaesthesia – (IM)

Dosage chart for 7.5mg ketamine/kg (duration of anaesthesia approximately 50 minutes)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
*Medetomidine (1mg/ml) – mls:-	0.04	0.12	0.20	0.40	0.60	0.80	1.00	1.20	1.60

**Ketmine (100mg/ml) – mls:-	0.08	0.23	0.38	0.75	1.13	1.50	1.88	2.25	3.00

* Based on a dose rate of 40µg medetomidine/kg bodyweight
** Based on a dose rate of 7.5mg ketamine/kg bodyweight

DOG - BUTORPHANOL/MEDETOMIDINE/KETAMINE

Dosage and administration: Administer butorphanol at a dose rate of 0.1mg/kg and medetomidine at a dose rate of 25µg/kg by intramuscular injection. The product should be administered 15 minutes following administration of butorphanol and medetomidine at a dose rate of 0.5ml/10kg bodyweight (equivalent to 5mg ketamine/kg) by intramuscular injection.

Effect: Following administration of butorphanol and medetomidine, dogs become recumbent in approximately 6 minutes and lose their pedal reflex in approximately 14 minutes. The pedal reflex returns approximately 53 minutes following administration of ketamine. Sternal recumbency is attained approximately 35 minutes later followed by standing a further 36 minutes later.

Butorphanol, medetomidine, and Ketamine Canine Anaesthesia - (IM)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
*Butorphanol (10mg/ml) – mls:-	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40
**Medetomidine (1mg/ml)– mls:	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
ADMINISTER BUTORPHANOL AND MEDETOMIDINE BY INTRAMUSCULAR INJECTION AT THE ABOVE DOSE RATES									
WAIT 15 MINUTES BEFORE ADMINISTERING KETAMINE BY IM INJECTION AT THE DOSE RATES BELOW									
***Ketmine (100mg/ml) – mls:-	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05

* Based on a dose rate of 0.1 mg butorphanol/kg bodyweight
** Based on a dose rate of 25µg medetomidine/kg bodyweight
*** Based on a dose rate of 5 mg ketamine/kg bodyweight

CAT – KETAMINE AS A SOLE AGENT

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

Effect: Duration of anaesthesia with the product is 20-40 minutes and recovery takes place over a 1-4 hour period.

Ketamine as a sole agent in cats

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
MINOR RESTRAINT *Ketamine (100mg/ml) – mls:-	0.16	0.22	0.27	0.33	0.38	0.44	0.49	0.55
MINOR SURGERY **Ketamine (100mg/ml) – mls:-	0.49	0.66	0.82	0.99	1.15	1.32	1.48	1.65

* Based on a dose rate of 11mg ketamine/kg bodyweight, suitable for minor restraint
** Based on a dose rate of 33mg ketamine/kg bodyweight, suitable for minor surgery and restraint of

fractious cats

CAT - ACEPROMAZINE/KETAMINE

Dosage and administration: Administer acepromazine at a dose rate of 0 0.11mg acepromazine/kg and atropine at a dose rate of 0.05mg/kg by intramuscular injection, as a premedicant to the product at a dose rate of 1.1ml/5kg bodyweight (equivalent to 22 mg ketamine/kg). Alternatively, administer simultaneously with the product using separate needles and syringes.

Acepromazine and Ketamine Feline Anaesthesia – (IM)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
*Acepromazine (0.2% soln) – mls:-	0.08	0.11	0.14	0.17	0.19	0.22	0.25	0.28
**Atropine (600µg/ml) – mls:-	0.13	0.17	0.21	0.25	0.29	0.34	0.38	0.42
***Ketamine (100mg/ml) – mls:-	0.33	0.44	0.55	0.66	0.77	0.88	0.99	1.10

* Based on a dose rate of 0.11mg acepromazine/kg bodyweight
** Based on a dose rate of 0.05mg atropine/kg bodyweight
*** Based on a dose rate of 22mg ketamine/kg bodyweight

CAT - XYLAZINE/KETAMINE

Dosage and administration: Administer xylazine at a dose rate of 1.1mg xylazine/kg and atropine at a dose rate of 0.03mg atropine/kg by intramuscular injection. Wait 20 minutes and then administer the product at a dose rate of 1.1ml/5kg bodyweight (equivalent to 22mg ketamine/kg), by intramuscular injection.

Effect: Xylazine may induce vomiting up to 20 minutes after administration. Onset of anaesthesia after intramuscular injection of ketamine takes 3-6 minutes. A xylazine/ketamine combination produces a deeper anaesthesia with more pronounced respiratory and cardiac effects and a longer recovery period than acepromazine/ketamine combinations.

Xylazine and Ketamine Feline Anaesthesia – (IM)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
Xylazine (2% soln) – mls:-	0.08	0.11	0.14	0.17	0.19	0.22	0.25	0.28
**Atropine (600µg/ml) – mls:-	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25
WAIT 20 MINUTES								
***Ketamine (100mg/ml) – mls:-	0.33	0.44	0.55	0.66	0.77	0.88	0.99	1.10

* Based on a dose rate of 1.1mg xylazine/kg bodyweight
** Based on a dose rate of 0.03mg atropine/kg bodyweight
*** Based on a dose rate of 22mg ketamine/kg bodyweight

CAT - MEDETOMIDINE/KETAMINE

Dosage and administration:

a) Intramuscular

Administer medetomidine at a dose rate of 80µg medetomidine/kg by intramuscular injection. This should be followed immediately by the intramuscular injection of the product at a dose rate of 0.12-0.38ml/5kg bodyweight (equivalent to 2.5mg up to a maximum of 7.5mg ketamine/kg).

Medetomidine and Ketamine Feline Anaesthesia – (IM)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
* Medetomidine (1mg/ml) – mls:-	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
**Ketamine(100mg/ml) – mls:-	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25

* Based on a dose rate of 80µg medetomidine/kg bodyweight
** Based on a dose rate of 5mg ketamine/kg bodyweight

b) Intravenous

Medetomidine and the product may be also administered by intravenous injection at the following dose rates; 40µg medetomidine/kg and 1.25mg ketamine/kg.

Medetomidine and Ketamine Feline Anaesthesia – (IV)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
* Medetomidine (1mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
**Ketamine (100mg/ml) – mls:-	0.02	0.03	0.03	0.04	0.05	0.05	0.06	0.06

* Based on a dose rate of 40µg medetomidine/kg bodyweight
** Based on a dose rate of 1.25mg ketamine/kg bodyweight

Effects: Onset of anaesthesia is 3-4 minutes (following IM). The duration of surgical anaesthesia varies between 30-60 minutes and is related to the dose of the product used. If required, anaesthesia may be prolonged with halothane and oxygen with or without nitrous oxide.

Atropine is not normally necessary when using a medetomidine/ketamine combination.

Clinical experience has shown that when ketamine and medetomidine have been used intravenously in cats and the need for anaesthesia has passed administration of 100µg atipamezole/kg by intramuscular injection results in recovery to sternal recumbency in approximately 10 minutes and to standing in approximately 14 minutes.

CAT - BUTORPHANOL/MEDETOMIDINE/KETAMINE

Dosage and administration:

a) Intramuscular

Administer butorphanol at a dose rate of 0.4mg/kg, medetomidine at a dose rate of 80µg/kg and the product at a dose rate of 0.25ml/5kg bodyweight (equivalent to 5mg ketamine/kg) by intramuscular injection.

Butorphanol, medetomidine, and Ketamine Feline Anaesthesia - (IM)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
*Butorphanol (10mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
** Medetomidine (1mg/ml) – mls:-	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
***Ketamine (100mg/ml) - mls	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25

* Based on a dose rate of 0.4 mg butorphanol/kg bodyweight
** Based on a dose rate of 80µg medetomidine/kg bodyweight
*** Based on a dose rate of 5 mg ketamine/kg bodyweight

b) Intravenous

Administer butorphanol at a dose rate of 0.1mg/kg, medetomidine at a dose rate of 40µg/kg and the product, depending on depth of anaesthesia required, at a dose rate of 0.06-0.13ml/5kg bodyweight (equivalent to 1.25-2.5mg ketamine/kg) by intravenous injection

Butorphanol, medetomidine, and Ketamine Feline Anaesthesia - (IV)

Dosage chart for 2.5 mg ketamine/kg (duration of anaesthesia approximately 28 minutes).

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
*Butorphanol (10mg/ml) – mls:-	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05
** Medetomidine (1mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
***Ketamine (100mg/ml) – mls:-	0.04	0.05	0.06	0.08	0.09	0.10	0.11	0.13

* Based on a dose rate of 0.1 mg butorphanol/kg bodyweight

** Based on a dose rate of 40µg medetomidine/kg bodyweight
*** Based on a dose rate of 2.5 mg ketamine/kg bodyweight

Effects: Cats become recumbent in 2-3 minutes following intramuscular injection. Loss of pedal reflex occurs 3 minutes post injection. At 45 minutes post induction, reversal with 200µg atipamezole/kg results in return of pedal reflex 2 minutes later, sternal recumbency 6 minutes later and standing 31 minutes later. The approximate time scales following intravenous administration are provided in the following table.

Approximate time scales when using the triple combination intravenously.

The Product* Dose mg/kg	Time to recumbency	Time to loss of pedal reflex	Time to return of pedal reflex	Time to sternal recumbency	Time to standing
1.25	32 secs	62 secs	26 mins	54 mins	74 mins
2.50	22 secs	39 secs	28 mins	62 mins	83mins

* In conjunction with butorphanol at 0.1 mg/kg and medetomidine at 40µg/kg

Clinical experience has shown that reversal, at any stage, with 100µg atipamezole/kg results in return of the pedal reflex 4 minutes later, sternal recumbency 7 minutes later and standing 18 minutes later.

HORSE - XYLAZINE/KETAMINE

Dosage and administration: Xylazine should be administered by slow intravenous injection at a dose rate of 1.1mg xylazine/kg. The product should be administered within 5 minutes of xylazine as an intravenous bolus at a dose rate of 2.2ml/100kg bodyweight (equivalent to 2.2mg ketamine/kg).

Effects: The horse should appear sedated by 2 minutes post injection of xylazine. Induction and recumbency take 1-2 minutes. Muscle jerking may occur in the first minutes, but this usually subsides. Anaesthesia is variable in duration, lasting between 10-30 minutes, but usually less than 20 minutes. Horses invariably stand 25-45 minutes after induction.

Recovery is generally quiet, but may occur suddenly. Therefore it is important that only short duration interferences are attempted, or that arrangements to prolong anaesthesia are made. For longer periods of anaesthesia, intubation and maintenance by inhalation anaesthesia can be used.

Xylazine and Ketamine Equine Anaesthesia – (IV)

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
+*Xylazine (10% soln) – mls:-	0.60	1.10	1.70	2.20	2.80	3.30	4.40	5.50	6.60
WAIT 2 MINUTES									
**Ketamine (100mg/ml) – mls:-	1.10	2.20	3.30	4.40	5.50	6.60	8.80	11.00	13.20

+ Administer xylazine, wait 2 minutes before administering ketamine
* Based on a dose rate of 1.1mg xylazine/kg bodyweight
** Based on a dose rate of 2.2mg ketamine/kg bodyweight

HORSE - DETOMIDINE/KETAMINE

Dosage and administration: Detomidine should be administered by intravenous injection at a dose rate of 20µg/kg. Allow five minutes for the horse to become deeply sedated then administer the product at a dose rate of 2.2ml/100kg bodyweight (equivalent to 2.2mg ketamine/kg) as an intravenous bolus.

Effect: Onset of anaesthesia is gradual; most horses take approximately 1 minute to become recumbent. Large, fit horses may take up to 3 minutes for recumbency. 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 after administration of the product surgical anaesthesia lasts for approximately 10-15 minutes.

Maintenance of surgical anaesthesia
Should it become necessary to prolong anaesthesia, either of the following regimes may be used:

i) Thiopental sodium
Thiopental sodium may be administered intravenously in boluses of 1mg/kg, as required. Total doses of 5mg/kg (five 1mg/kg increments) have been given. Total doses greater than this may reduce the quality of recovery. Thiopental sodium can also be administered in increments if sufficient depth of anaesthesia is not achieved. The horse may be ataxic if encouraged to stand prematurely and so should be left to stand in its own time.

ii) Detomidine/Ketamine
Administer 10µg detomidine/kg (50% the initial premedication dose) by intravenous injection, followed immediately by 1.1mg ketamine/kg (50% the initial induction dose) by intravenous injection. This will provide approximately 10 minutes additional surgical anaesthesia, which can be repeated at regular 10 minute intervals (up to 5 times) without compromising recovery.

Detomidine and Ketamine Equine Anaesthesia – (IV)

Premedication and Induction of Anaesthesia

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
*Detomidine (10mg/ml)– mls:	0.10	0.20	0.30	0.40	0.50	0.60	0.80	1.00	1.20
WAIT 5 MINUTES									
**Ketamine(100mg/ml) – mls:	1.10	2.20	3.30	4.40	5.50	6.60	8.80	11.00	13.20

Induction – administer detomidine IV, wait 5 minutes before administering ketamine IV
* Based on a dose rate of 20µg detomidine/kg bodyweight
** Based on a dose rate of 2.2mg ketamine/kg bodyweight

Top-up (Maintenance) dose at 10 minute intervals

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
~Detomidine(10mg/ml)– mls:-	0.05	0.10	0.15	0.20	0.25	0.30	0.40	0.50	0.60
~~Ketamine(100mg/ml)– mls:	0.55	1.10	1.65	2.20	2.75	3.30	4.40	5.50	6.60

Maintenance - administer detomidine IV, immediately followed by ketamine IV
~ Based on a dose rate of 10µg detomidine/kg bodyweight
~~ Based on a dose rate of 1.1mg ketamine/kg bodyweight

HORSE - ROMIFIDINE/KETAMINE
Dosage and administration: Administer romifidine by intravenous injection at a dose rate of 100µg romifidine/kg. After 5-10 minutes, administer the product at a dose rate of 2.2ml/100kg (equivalent to 2.2mg ketamine/kg) as an intravenous bolus. Sedation should be apparent before the induction of anaesthesia.

Maintenance of surgical anaesthesia
Should it become necessary to prolong anaesthesia, either of the following regimes may be used:

i) Thiopental sodium

Thiopental sodium may be administered intravenously in boluses of 2.5mg/kg when signs of returning consciousness appear. This can be repeated up to 3 times after induction. Total doses greater than this may reduce the quality of recovery. The horse may be ataxic if encouraged to stand prematurely and so should be left to stand in its own time.

ii) Romifidine/Ketamine
Depending on depth and duration of anaesthesia required, administer romifidine intravenously within the dose range of 25-50µg/kg bodyweight (¼-½ the initial premedication dose) followed immediately by ketamine intravenously at a dose rate of 1.1mg/kg bodyweight (½ the initial induction dose). Each top-up lasts approximately 8-10 minutes and can be repeated at regular 8-10 minute intervals (up to 5 times) without compromising recovery.

Romifidine and Ketamine Equine Anaesthesia – (IV)

Premedication and Induction of Anaesthesia

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
* Romifidine (10mg/ml) – mls:-	0.50	1.00	1.50	2.00	2.50	3.00	4.00	5.00	6.00
WAIT 5-10 MINUTES									
**Ketamine (100mg/ml) – mls:-	1.10	2.20	3.30	4.40	5.50	6.60	8.80	11.00	13.20

Induction - administer romifidine IV, wait 5-10 minutes before administering ketamine IV
* Based on a dose rate of 100µg romifidine/kg bodyweight
** Based on a dose rate of 2.2mg ketamine/kg bodyweight

Top-up (Maintenance) dose at 8-10 minute intervals

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
~ Romifidine (10mg/ml) – mls:-	0.25	0.50	0.75	1.00	1.25	1.5	2.00	2.5	3.00
~~Ketamine (100mg/ml) – mls:	0.55	1.10	1.65	2.20	2.75	3.30	4.40	5.50	6.60

Maintenance – administer romifidine IV, immediately followed by ketamine IV
~ Based on a dose rate of 50µg romifidine/kg bodyweight
~~ Based on a dose rate of 1.1mg ketamine/kg bodyweight

SUB-HUMAN PRIMATES

The usual therapeutic dose for restraint and minor surgical procedures in primates is 3-15mg/kg administered intramuscularly. The veterinary medicinal product (11mg ketamine/kg or 1.1ml/10kg) and acepromazine (0.55mg/kg or 2.8ml/10kg) administered intramuscularly to rhesus monkeys results in a smooth induction with anaesthesia attained in less than 5 minutes. The average duration of anaesthesia is just under one hour. Information on dosage rates for individual species can be obtained from the Marketing Authorisation Holder.

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

Respiratory depression may occur following administration of high doses of ketamine
If necessary, suitable artificial aids to maintain ventilation and cardiac output should be used until sufficient detoxification has taken place to enable a return to adequate spontaneous ventilation and cardiac activity. Pharmacological cardiac stimulants are not recommended, unless no other supportive measures are available.

4.11 Withdrawal period(s)

Horse: Meat and offal: zero days

Milk: zero days

5. PHARMACOLOGICAL PROPERTIES

The product is a dissociative anaesthetic agent for use by intramuscular, subcutaneous or intravenous injection.

The product induces a state of catalepsy with amnesia and analgesia; muscle tone is maintained including the pharyngeal and laryngeal reflexes. The heart rate, blood pressure and cardiac output are increased; respiratory depression is not a noticeable feature. All these characteristics may be modified if the product is used in combination with other agents.

ATCVet Code: QN01AX03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzethonium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 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.
Following withdrawal of the first dose use the product within 28 days. Discard any unused material.

6.5 Nature and composition of immediate packaging

Clear colourless type I glass vials with rubber stoppers and aluminium flip off seals containing 10ml or 50ml of colourless solution.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

8. MARKETING AUTHORISATION NUMBER(S)

VPA10387/036/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/03/2015

10 DATE OF REVISION OF THE TEXT

03/01/2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.
For administration only by a veterinarian.