ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, CY, DE, ES, PT, RO
Ketaset 100 mg/ml solution for injection for dogs, cats and horses.

UK, CY, EL, IE
Ketavet 100 mg/ml solution for injection for dogs, cats and horses.

IT
Ketastesic Vet 100 mg/ml solution for injection for dogs, cats and horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:	
Ketamine:	100 mg
(Equivalent to ketamine hydrochloride)	115.35 mg
Excipient(s):	
Benzethonium chloride:	0.10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution, free from visible evidence of contamination.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats and horses.

4.2 Indications for use, specifying the target species

The product may be used to induce anaesthesia:
a) in conjunction with butorphanol and medetomidine in the dog and cat,
b) in conjunction with xylazine in the dog, cat and horse,
c) in conjunction with detomidine in the horse,
d) in conjunction with romifidine in the horse.

Based on the benefit/risk assessment performed by the veterinarian the product may be used as a sole agent for restraint and minor surgical procedures where muscle relaxation is not required in the domestic cat.

4.3 Contraindications

Do not use in animals with pre-existing hepatic or renal pathology.

Do not use in animals with severe cardiac de-compensation or with apparent high blood pressure or glaucoma.
Do not reverse ketamine combinations in dogs with atipamezole.
Do not use ketamine as a sole agent in dogs or horses.
Do not use in animals with eclampsia or pre-eclampsia.
Do not use for surgical intervention on pharynx, larynx, trachea or bronchial tree, if sufficient relaxation is not ensured by administration of a muscle relaxant (intubation obligatory).
Do not use in cases of hypersensitivity to the active substance or to the excipient.

4.4 Special warnings for each target species

For very painful and major surgical interventions, as well as for maintenance of anaesthesia, a combination with injectable or inhalation anaesthetics is necessary.
For surgical and diagnostic procedures requiring muscle relaxation, the concomitant use of muscle-relaxants is necessary.
For improvement of anaesthesia or prolongation of effect ketamine can be combined with α_2-receptor-agonists, anaesthetics, neuroleptanalgesics, tranquilizers and inhalational anaesthetic agents.
Please see section 4.8.

4.5 Special precautions for use

Special precautions for use in animals

It is generally accepted as good anaesthetic practice to fast animals for a period prior to anaesthesia where possible.
Induction and recovery should be allowed to occur in quiet and calm surroundings.
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.
Atropine premedication may reduce salivation in cats. Since use of atropine with alpha-2-agonists, which are often administered with ketamine, may increase arterial blood pressure, heart rate and the incidence of arrhythmias, atropine premedication should only be used according to a benefit-risk assessment by the responsible veterinarian.
Muscular twitching and tonic convulsions have been reported in the cat at recommended dose rates. These subside spontaneously but may be prevented by use of xylazine premedication, or controlled by use of 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 or using appropriate ointments.
Ketamine may exhibit pro-convulsant and anti-convulsant properties, and therefore should be used with care in patients with seizure disorders.
Ketamine may increase intracranial pressure and therefore, may not be suitable for patients with cerebrovascular insults.
Ketamine should be used with caution when pulmonary disease is present or suspected.
Muscle relaxation is not achieved with ketamine alone.
When used in combination with other products, consult the contra-indications and warnings that appear on the relevant data sheets.

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.
Preferably use a guarded needle until the moment of injection.
People with known hypersensitivity to ketamine or to any excipient should avoid contact with the veterinary medicinal product.
Avoid contact with the skin and eyes. Wash any splashes from skin and eyes immediately with large amounts of water.
In case of accidental self-injection, or if symptoms occur after ocular/oral contact, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE.
Adverse effects on the foetus cannot be excluded. The veterinary medicinal product should not be administered by pregnant women.
Advice to doctors:
Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

4.6 Adverse reactions (frequency and seriousness)

Some pain after intramuscular injection may be observed very rarely.
Salivation in cats may be observed in very rare cases. Atropine premedication may reduce this side effect.
Muscular twitching and tonic convulsions have been reported very rarely in cats and dogs at recommended dose rates.
The eyes remain open and the pupils dilated (mydriasis) in very rare cases in cats and dogs. Nystagmus may also be observed.
Dose-dependent respiratory depression may occur very rarely. When given too rapidly or in excessive doses, significant respiratory depression may occur.
Increased heart rate and arterial blood pressure have been reported in very rare cases.
Emergence reactions - ataxia, hypersensitivity to stimuli, excitation – may occur very rarely during recovery.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Use of the product has not been assessed during pregnancy and lactation.
Due to transfer of ketamine across the placental barrier, foetal anaesthesia and respiratory depression in neonates may occur.
Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Care should be taken when using ketamine-halothane combinations since the half-life of ketamine is prolonged. Neuroleptanalgesics, tranquilizers, morphine analogues and chloramphenicol potentiate ketamine anaesthesia. Barbiturates and opiates can prolong the recovery period.
Please see section 4.4

4.9 Amounts to be administered and administration route

It should be noted that dosage and routes of administration vary widely between species.
Dogs: intramuscular use,
Cats: intramuscular, intravenous or subcutaneous use,
Horses: intravenous use only.

The cap may be safely punctured up to 20 times.

DOG - XYLAZINE/KETAMINE

Dosage and administration: Administer xylazine at a dose rate of 1 mg xylazine/kg by intramuscular injection. Immediately administer the product at a dose rate of 15 mg ketamine/kg (equivalent to 1.5 ml/10 kg bodyweight) 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 40 µg medetomidine/kg and the product at a dose rate of 5.0-7.5 mg ketamine/kg bodyweight (equivalent to 0.5-0.75 ml/10 kg), depending on duration of anaesthesia required, by intramuscular injection.

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

Medetomidine and Ketamine Canine Anaesthesia – (IM)

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

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
*Medetomidine (1 mg/ml) – mls:-	0.04	0.12	0.20	0.40	0.60	0.80	1.00	1.20	1.60
**Ketamine (100 mg/ml) –	0.0	0.1	0.2	0.5	0.7	1.0	1.2	1.5	2.0

mls:-	5	5	5	0	5	0	5	0	0
DO NOT REVERSE WITH ATIPAMEZOLE									

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

Medetomidine and Ketamine Canine Anaesthesia – (IM)

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

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
*Medetomidine (1 mg/ml) – mls:-	0.04	0.12	0.20	0.40	0.60	0.80	1.00	1.20	1.60
**Ketamine (100 mg/ml) – mls:-	0.08	0.23	0.38	0.75	1.13	1.50	1.88	2.25	3.00
DO NOT REVERSE WITH ATIPAMEZOLE									

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

DOG - BUTORPHANOL/MEDETOMIDINE/KETAMINE

Dosage and administration: Administer butorphanol at a dose rate of 0.1 mg/kg and medetomidine at a dose rate of 25 µg/kg by intramuscular injection. Ketamine injection should be administered 15 minutes following administration of butorphanol and medetomidine at a dose rate of 5 mg ketamine/kg (equivalent to 0.5 ml/10 kg bodyweight) 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 (10 mg/ml) – mls:-	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40
**Medetomidine (1 mg/ml) – mls:-	0.03	0.08	0.13	0.25	0.38	0.50	0.63	0.75	1.00
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									
***Ketamine (100 mg/ml) - mls	0.05	0.15	0.25	0.50	0.75	1.00	1.25	1.50	2.00
DO NOT REVERSE WITH ATIPAMEZOLE									

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

CAT – KETAMINE AS A SOLE AGENT

Mono-anaesthetic use of ketamine is possible, but to avoid undesired psycomotoric effects combined anaesthesia is recommended.

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 11-33 mg ketamine/kg depending on the degree of restraint or surgical interference that is intended.

Ketamine as a sole agent in cats – (IM, IV, SC)

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

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

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

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

For major surgery, ketamine should be used in conjunction with supplemental sedatives or anesthetics. Dosage varies from 1.25-22 mg/kg (0.06-1.1 ml/5 kg) depending on the combination and route of administration used.
Vomiting is unlikely to occur when ketamine is used alone, however, cats should be starved for several hours prior to anaesthesia where possible.

Acepromazine pre-medication with ketamine as a sole agent: Acepromazine can be administered by intramuscular injection, as premedication. Endotracheal intubation can be achieved during ketamine anaesthesia. Inhalation anaesthesia may be maintained by suitable combinations of methoxyflurane, halothane, nitrous oxide and oxygen.

CAT - XYLAZINE/KETAMINE

Dosage and administration: Administer xylazine at a dose rate of 1.1 mg xylazine/kg (corresponding to 0.28 ml/5 kg bodyweight of xylazine 2% solution). Wait 20 minutes and then administer the product at a dose rate of 22 mg ketamine/kg bodyweight (equivalent to 1.1 ml/5 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
WAIT 20 MINUTES								
**Ketamine (100 mg/ml) – mls:-	0.33	0.44	0.55	0.66	0.77	0.88	0.99	1.10

* Based on a dose rate of 1.1 mg xylazine/kg bodyweight

**Based on a dose rate of 22 mg ketamine/kg bodyweight

CAT - MEDETOMIDINE/KETAMINE

Dosage and administration:

a) Intramuscular

Administer medetomidine at a dose rate of 80 µg medetomidine/kg by intramuscular injection. This should be followed immediately by the intramuscular injection of the product at a dose rate of 2.5 mg up to a maximum of 7.5 mg ketamine/kg bodyweight (equivalent to 0.12-0.38 ml/5 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 (1 mg/ml) – mls:-	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
**Ketamine(100 mg/ml) – mls:-	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25

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

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

b) Intravenous

Medetomidine and the product may be also administered by intravenous injection at the following dose rates; 40 µg medetomidine/kg and 1.25 mg 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 (1 mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
**Ketamine (100 mg/ml) – mls:-	0.02	0.03	0.03	0.04	0.05	0.05	0.06	0.06

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

** Based on a dose rate of 1.25 mg 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 0.4 mg/kg, medetomidine at a dose rate of 80 µg/kg and the product at a dose rate of 5 mg ketamine/kg bodyweight (equivalent to 0.25 ml/5 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 (10 mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
** Medetomidine (1 mg/ml) – mls:-	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
***Ketamine (100 mg/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 80 µg 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 40 µg/kg and the product, depending on depth of anaesthesia required, at a dose rate of 1.25-2.5mg ketamine/kg bodyweight (equivalent to 0.06- 0.13ml/5kg) by intravenous injection.

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

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

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

* 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 200 µg 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 40 µg/kg

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

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 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 lidocaine between the testicles eliminates the possible response to ligation of the testicular cord and minimises the number of top-ups required.

HORSE - XYLAZINE/KETAMINE

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

** Based on a dose rate of 2.2 mg ketamine/kg bodyweight

HORSE - DETOMIDINE/KETAMINE

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

ii) Detomidine/Ketamine
Administer 10 µg detomidine/kg (50% the initial premedication dose) by intravenous injection, followed immediately by 1.1 mg 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 (10 mg/ml) – mls:-	0.10	0.20	0.30	0.40	0.50	0.60	0.80	1.00	1.20
WAIT 5 MINUTES									
**Ketamine(100 mg/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 20 µg detomidine/kg bodyweight
** Based on a dose rate of 2.2 mg 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 10 µg detomidine/kg bodyweight
~~ Based on a dose rate of 1.1 mg ketamine/kg bodyweight

HORSE - ROMIFIDINE/KETAMINE

Dosage and administration: Administer romifidine by intravenous injection at a dose rate of 100 µg romifidine/kg. The horse should appear sedated by 5-10 minutes after injection. At this stage administer the product at a dose rate of 2.2 mg ketamine/kg (equivalent to 2.2 ml/100kg) 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 to prolong anaesthesia.

ii) Romifidine/Ketamine

Depending on depth and duration of anaesthesia required, administer romifidine intravenously within the dose range of 25-50 µg/kg bodyweight (25-50% of the initial premedication dose) followed immediately by ketamine intravenously at a dose rate of 1.1 mg/kg bodyweight (50% of 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 (10 mg/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 (100 mg/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 100 µg romifidine/kg bodyweight

** Based on a dose rate of 2.2 mg 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 (10 mg/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 50 µg romifidine/kg bodyweight

~~ Based on a dose rate of 1.1 mg ketamine/kg bodyweight

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

Overdose of ketamine may result in CNS effects (eg seizures), apnoea, arrhythmia and dysphagia.

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)

Horses (meat and offal): 1 day
(milk): 24 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Nervous system; anaesthetics, general; other general anaesthetics; ketamine
ATCvet Code. QN01AX03

5.1. Pharmacodynamic 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.

5.2. Pharmacokinetic particulars

Ketamine is distributed to all body tissues rapidly after intravenous administration, with the highest levels found in the brain, liver, lung and fat. Plasma protein binding is approximately 53% in the dog, 37-53% in the cat and 50% in the horse. In most species, ketamine is metabolised in the liver and these metabolites, along with unmetabolised ketamine, are eliminated in urine. In cats, ketamine is almost exclusively excreted unchanged in the urine. The elimination half-life in the cat and the horse has been reported to be approximately 1 hour. The redistribution of ketamine out of the CNS is more of a factor in determining duration of anaesthesia than the elimination half-life.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzethonium chloride
Water for injections

6.2 Major incompatibilities

Due to a chemical incompatibility, do not mix barbiturates or diazepam with ketamine in the same syringe.

Do not mix with any other veterinary medicinal product.

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 freeze.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Clear colourless type I glass vials with chlorobutyl rubber stoppers and aluminium flip off seals.

Pack sizes:
Box with 1 vial of 10 ml
Box with 1 vial of 50 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 subsidiaries in the concerned European Union Member States

8. MARKETING AUTHORISATION NUMBER(S)

TBA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

TBA

10 DATE OF REVISION OF THE TEXT

TBA

PROHIBITION OF SALE, SUPPLY AND/OR USE