[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketamidor 100 mg/ml solution for injection (AT, BE, CZ, DE, EE, EL, ES, FR, HU, IE, NL, PL, PT, SI, UK(NI))

Ketador vet. 100 mg/ml solution for injection (DK, IS, SE, FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ketamine (as hydrochloride) 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzethonium chloride	0.1 mg
Water for injections	

Clear, colourless to almost colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs, dogs, cats.

3.2 Indications for use for each target species

To be used as a sole agent for restraint and minor surgical procedures in the cat, where muscle relaxation is not required.
To be used to induce anaesthesia:

a) in combination with detomidine in the horse.
b) in combination with xylazine in the horse, in cattle, dog and in the cat.
c) in combination with azaperone in the pig.
d) in combination with medetomidine in the dog and cat.
e) in combination with diazepam in the dog.

3.3 Contraindications

Do not use:

- in animals with severe cardiac de-compensation, suspected pulmonary disease, apparent high blood pressure, or cerebrovascular insults.
- in animals with pre-existing liver and kidney pathology.
- in eclampsia, pre-eclampsia, glaucoma and seizure disorders (e.g. epilepsy).
- for surgical intervention on pharynx, larynx, trachea or bronchial tree, if sufficient relaxation is not ensured by administration of a muscle relaxant (intubation obligatory).
- in animals undergoing a myelogram procedure.

Do not use in cases of hypersensitivity to the active substance or to the excipient.
Do not use the veterinary medicinal product as a sole anaesthetic agent in any other species apart from

the cat.

3.4 Special warnings

For very painful and major surgical interventions, as well as for maintenance of anaesthesia, a combination with injectable- or inhalation-anaesthetics is necessary. As muscle relaxation required for surgical procedures cannot be achieved with ketamine alone, additional muscle-relaxants should be used concomitantly. For improvement of anaesthesia or prolongation of effect ketamine can be combined with α_2-receptor-agonists, anaesthetics, neuroleptanalgesics, tranquilizers and inhalational anaesthetic agents.
A small proportion of animals have been reported to be unresponsive to ketamine as an anaesthetic agent at normal dosages.
It should be noted that time-to-full-effect may be prolonged when using the subcutaneous administration route in cat.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not reverse ketamine-medetomidine combinations in dogs and cats with atipamezole until 45 minutes after ketamine administration, when ketamine action has ceased.

Pre-surgical preparation:
As for all anaesthetics animals should be fasted for 12 hours before ketamine anaesthesia.

Anaesthetic period:
Under ketamine anaesthesia the eyes of treated animals remain open, therefore to prevent desiccation in case of longer lasting procedures they should be protected accordingly (by use of appropriate ointments).

Recovery period:
It is important that both premedication and recovery should occur in quiet and calm surroundings.
Recovery usually is complete after 2 hours but may occasionally take longer. In dogs, states of psychomotoric excitation with howling can rarely be observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to ketamine or to the 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.
Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the veterinary medicinal product.
This is a potent drug - particular care should be taken to avoid accidental self-administration.
In cases 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.

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

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, cattle, pigs, dogs, cats:

Rare (1 to 10 animals / 10 000 animals treated):	Tachycardia, Hypertension, Increased salivation[1]
Undetermined frequency (cannot be estimated from the available data):	Immediate pain upon injection[2], Muscular hypertonicity[3], Muscle tremor[4], Convulsion[4,5], Nystagmus[6], Mydriasis[6], Hyperaesthesia, Increased sensitivity to sound[7], Excitation[8], Respiratory depression[9], Respiratory arrest[10]

[1] Due to brainstem stimulation.
[2] During intramuscular injection.
[3] Due to disinhibition of the extra pyramidal system.
[4] When no concomitant muscle relaxant is administered.
[5] Tonic-clonic.
[6] The eyes remain open.
[7] During anaesthesia and in the recovery period.
[8] Motoric.
[9] Dose-related. Combination with respiratory depressant products may increase this respiratory effect.
[10] Particularly in cats.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:
Ketamine crosses the placental barrier. Use only according to the benefit-risk assessment by the responsible veterinarian. Ketamine should not be used in the periparturient period.

Lactation:
Use during lactation only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Neuroleptanalgesics, tranquilizers, morphine analogues, cimetidine and chloramphenicol potentiate ketamine anaesthesia.
Barbiturates and opiates or diazepam can prolong the recovery period. Effects may be additive; dosage reduction of one or both agents may be required. Potential for increased risk for arrhythmias when used in combination with thiopental or halothane. Halothane prolongs the half-life of ketamine.
Simultaneously administered intravenous spasmolytics can provoke a collapse.
Theophylline with ketamine can cause an increased incidence of seizures.
The use of detomidine in combination with ketamine gives a slow recuperation.

3.9 Administration routes and dosage

For intravenous use (i.v.): horses, cattle, dogs and cats.
For intramuscular use (i.m.): pigs, dogs and cats.

For subcutaneous use (s.c.): cats.

Ketamine can show large inter-individual variation in effect, and therefore dose rates administered should be tailored to the individual animal, dependent on factors such as age, condition, and the depth and duration of anaesthesia required. Prolongation of effect is possible by repeated administration of an optionally reduced initial dose.

For combination use: before ketamine is administered, please ensure that the animals are adequately sedated.

Horses
Pre-medication with a sedative is required for a sufficient anaesthetic effect:

To induce anaesthesia
With detomidine
Detomidine 20 µg/kg i.v., after 5 minutes
Ketamine 2.2 mg/kg fast i.v. (2.2 ml/100 kg)
Onset of action is gradual, taking approximately 1 minute to attain recumbency, with duration of anaesthetic effect lasting approximately 10 - 15 minutes.

With xylazine
Xylazine 1.1 mg/kg i.v., followed by
Ketamine 2.2 mg/kg i.v. (2.2 ml/100 kg)
Onset of action is gradual, taking approximately 1 minute, with duration of anaesthetic effect being variable and lasting 10 - 30 minutes but usually less than 20 minutes.

After injection the horse lays down spontaneously without any further help. If a distinct muscle relaxation is required simultaneously, muscle relaxants can be administered to the recumbent animal, until the horse shows first symptoms of relaxation.

Cattle
To avoid uncontrolled lying down and possible symptoms of excitation or for potentiation of anaesthesia a sedative premedication is recommended. To avoid hypoxia due to lateral or dorsal recumbency, oxygen can be administered through a nasal tube.

To induce anaesthesia
With xylazine
Xylazine 0.14 - 0.22 mg/kg i.v./i.m., followed by
Ketamine 2 - 5 mg/kg i.v. (2 - 5 ml/100 kg)
Onset of action is approximately 1 minute, with duration of anaesthetic effect lasting approximately 30 minutes.

The lower end of the stated dose range should be used when administering xylazine via the intravenous route.

Pigs
To induce anaesthesia
With azaperone
Ketamine 15 - 20 mg/kg i.m. (1.5 - 2 ml/10 kg) and 2 mg/kg azaperone i.m..
In 4 – 5 month old pigs, following administration of 2 mg/kg azaperone and 20 mg/kg ketamine i.m.,
the onset of anaesthesia took on average 29 minutes and duration of effect lasted about 27 minutes.

Dogs
Ketamine cannot be used as a mono-anaesthetic in dogs, as it causes an increased muscle tone and

uncoordinated muscle contractions.

To induce anaesthesia
With medetomidine
Medetomidine 40 µg/kg i.m., followed by
Ketamine 5 - 7.5 mg/kg i.m. (0.5 - 0.75 ml/10 kg)
Duration of effect varies between 30 - 50 minutes and is dose related.

With xylazine
Xylazine 2 mg/kg i.m., after 10 minutes
Ketamine 10 mg/kg i.m. (1 ml/10 kg).
In dogs weighing more than 25 kg bodyweight reduce xylazine dosage to 1.3 mg/kg.
Onset of action is usually within 10 minutes and duration of effect lasts for approximately 30 minutes.

With diazepam
Administer diazepam 0.25 mg/kg i.v., immediately followed by
Ketamine 5 mg/kg i.v. (0.5 ml/10 kg).
Ketamine should be injected slowly and generally administered to effect, when used intravenously. Appropriate premedication should be used to ensure adequate sedation before administration of the diazepam-ketamine combination and to facilitate intubation. The optimal dosing regimen should be individually based on the pre-medication used. Average duration of effect is 10-20 minutes.

Cats
Mono-anaesthetic use of ketamine is possible, but to avoid undesired psychomotoric effects combined anaesthesia is recommended. Ketamine on its own may be used by intravenous injection, but intramuscular injection is the recommended route.
Ketamine should be injected slowly when administered intravenously.

As a sole agent
11 mg/kg ketamine i.m./i.v. for minor restraint,
22 - 33 mg/kg ketamine i.m./i.v. for minor surgery and restraint of fractious cats.
Duration of ketamine anaesthesia is 20 – 40 minutes and recovery takes place over a 1 – 4 hour period.

To induce anaesthesia (anaesthesia < 1 hour)
With medetomidine
Medetomidine 80 µg/kg i.m., followed by
Ketamine 5 – 7.5 mg/kg i.m. (0.25 - 0.4 ml/5 kg)
Onset of action is usually 3 - 4 minutes and duration of effect varies between 30 - 60 minutes and is dose related.

With xylazine
Xylazine 1 - 2 mg/kg i.m./s.c. and
Ketamine 10 - 20 mg/kg i.m./s.c. (0.5 - 1 ml/5 kg)
The lowest dose of xylazine (1 mg/kg) should be used, if ketamine is used at the highest dose (20 mg/kg).
Onset of action is usually within 5 minutes of ketamine administration and duration of effect lasts for at least 30 minutes.

Due to low dose volumes, the use of suitably calibrated measuring equipment, e.g. an insulin type syringe, is recommended.

The rubber stopper can be punctured safely a maximum of 25 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In cases of overdose cardiac arrhythmia and respiratory depression up to paralysis may occur. If necessary, suitable artificial aids to maintain ventilation and cardiac output should be used until sufficient detoxification has taken place. Pharmacological cardiac stimulants are not recommended, unless no other supportive measures are available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Horses and cattle:
Meat and offal: zero days
Milk: zero hours

Pigs:
Meat and offal: zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN01AX03.

4.2 Pharmacodynamics

Ketamine is a potent dissociative anaesthetic agent. The veterinary medicinal 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 veterinary medicinal product is used in combination with other agents.

4.3 Pharmacokinetics

Ketamine is distributed quickly and completely in the organism. It passes the placenta, but concentrations in the foetus are much lower than blood concentration in the dam. Protein binding in blood is about 50 %. Distribution in tissue is irregular, highest concentrations were found in liver and kidney. It is quickly and completely metabolised, but metabolism differs between individual animal species. Excretion is mainly renal.

In horses (after a single dose of 2.2 mg/kg i.v. ketamine) a C_{max} of 685 +/- 147 ng/ml is observed, with T_{max} being reached at 2h. In cattle (after a single dose of 5 mg/kg i.v.) C_{max} is 18,135 ng/ml, with T_{max} = 0.083 h. In pigs a C_{max} of 11.6 µg/ml is observed, with T_{max} being reached after 5 minutes after a single dose of 15 mg/kg i.m.. In the target animal species dog and cat after administration of 20 mg/kg i.v., peak tissue levels are 42 % of the original dose, with T_{max} being reached within 10 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3 Special precautions for storage

Keep the container in the outer carton in order to protect from light. After first opening do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Clear glass vial, type I (Ph. Eur.) with bromobutyl-rubber stopper type I (Ph.Eur.) and aluminium cap, packed in a cardboard box.

Package sizes: 1 x 10 ml, 5 x 10 ml, 1 x 50 ml
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}.>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 10 ml, 5 x 10 ml, 1 x 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketamidor 100 mg/ml solution for injection (AT, BE, CZ, DE, EE, EL, ES, FR, HU, IE, NL, PL, PT, SI, UK(NI))
Ketador vet. 100 mg/ml solution for injection (DK, IS, SE, FI)

Ketamine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ketamine (as hydrochloride) 100 mg

3. PACKAGE SIZE

10 ml
50 ml
5 x 10 ml

4. TARGET SPECIES

Horses, cattle, pigs, dogs, cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses, cattle, dogs, cats: i.v. / pigs, dogs, cats: i.m. / cats: s.c.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal:	zero days
Milk:	zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton in order to protect from light. After first opening do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBERS

XXXX

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml and 50 ml clear glass vial type I with brombutyl rubber stopper and alu caps

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketamidor (AT, BE, CZ, DE, EE, EL, ES, FR, HU, IE, NL, PL, PT, SI, UK(NI))

Ketador vet. (DK, IS, SE, FI)

Horses, cattle, pigs, dogs, cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ketamine 100 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use by…

10 ml
50 ml

VetViva Richter (logo)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ketamidor 100 mg/ml solution for injection (AT, BE, CZ, DE, EE, EL, ES, FR, HU, IE, NL, PL, PT, SI, UK(NI))

Ketador vet. 100 mg/ml solution for injection (DK, IS, SE, FI)

2. Composition

Each ml contains:

Active substances:
Ketamine (as hydrochloride) 100 mg

Excipients:
Benzethonium chloride 0.1 mg

Clear, colourless to almost colourless solution.

3. Target species

Horses, cattle, pigs, dogs, cats.

4. Indications for use

To be used as a sole agent for restraint and minor surgical procedures in the cat, where muscle relaxation is not required.
To be used to induce anaesthesia:

a) in combination with detomidine in the horse.
b) in combination with xylazine in the horse, in cattle, dog and in the cat.
c) in combination with azaperone in the pig.
d) in combination with medetomidine in the dog and cat.
e) in combination with diazepam in the dog.

5. Contraindications

Do not use:
- in animals with severe cardiac de-compensation, suspected pulmonary disease, apparent high blood pressure, or cerebrovascular insults.
- in animals with pre-existing liver and kidney pathology.
- in eclampsia, pre-eclampsia, glaucoma and seizure disorders (e.g. epilepsy).
- for surgical intervention on pharynx, larynx, trachea or bronchial tree, if sufficient relaxation is not ensured by administration of a muscle relaxant (intubation obligatory).
- in animals undergoing a myelogram procedure.

Do not use in cases of hypersensitivity to the active substance or to the excipient.
Do not use the veterinary medicinal product as a sole anaesthetic agent in any other species apart from the cat.

6. Special warnings

Special warnings:
For very painful and major surgical interventions, as well as for maintenance of anaesthesia, a combination with injectable- or inhalation-anaesthetics is necessary. As muscle relaxation required for surgical procedures cannot be achieved with ketamine alone, additional muscle-relaxants should be used concomitantly. For improvement of anaesthesia or prolongation of effect ketamine can be combined with α_2-receptor-agonists, anaesthetics, neuroleptanalgesics, tranquilizers and inhalational anaesthetic agents.
A small proportion of animals have been reported to be unresponsive to ketamine as an anaesthetic agent at normal dosages.
It should be noted that time-to-full-effect may be prolonged when using the subcutaneous administration route in cat.

Special precautions for safe use in the target species:
Do not reverse ketamine-medetomidine combinations in dogs and cats with atipamezole until 45 minutes after ketamine administration, when ketamine action has ceased.

Pre-surgical preparation:
As for all anaesthetics animals should be fasted for at least 12 hours before ketamine anaesthesia.

Anaesthetic period:
Under ketamine anaesthesia the eyes of treated animals remain open, therefore to prevent desiccation in case of longer lasting procedures they should be protected accordingly (by use of appropriate ointments).

Recovery period:
It is important that both premedication and recovery should occur in quiet and calm surroundings.
Recovery usually is complete after 2 hours but may occasionally take longer. In dogs, states of psychomotoric excitation with howling can rarely be observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to ketamine or to the 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.
Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the veterinary medicinal product.
This is a potent drug - particular care should be taken to avoid accidental self-administration.
In cases 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.

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Ketamine crosses the placental barrier. Ketamine should not be used in the periparturient period.
The use of the veterinary medicinal product should be on the basis of a risk-benefit analysis by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Neuroleptanalgesics, tranquilizers, morphine analogues, cimetidine and chloramphenicol potentiate ketamine anaesthesia.

Barbiturates and opiates or diazepam can prolong the recovery period. Effects may be additive; dosage reduction of one or both agents may be required. Potential for increased risk for arrhythmias when used in combination with thiopental or halothane. Halothane prolongs the half-life of ketamine.
Simultaneously administered intravenous spasmolytics can provoke a collapse.
Theophylline with ketamine can cause an increased incidence of seizures.
The use of detomidine in combination with ketamine gives a slow recuperation.

Overdose:
In cases of overdose cardiac arrhythmia and respiratory depression up to paralysis may occur. If necessary, suitable artificial aids to maintain ventilation and cardiac output should be used until sufficient detoxification has taken place. Pharmacological cardiac stimulants are not recommended, unless no other supportive measures are available.

<Special restrictions for use and special conditions for use:>

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

7. Adverse events

Horses, cattle, pigs, dogs, cats:
Rare (1 to 10 animals / 10 000 animals treated):
Tachycardia, Hypertension, Increased salivation[1].

Undetermined frequency (cannot be estimated from the available data):
Immediate pain upon injection[2], Muscular hypertonicity[3], Muscle tremor[4], Convulsion[4,5], Nystagmus[6], Mydriasis[6], Hyperaesthesia, Increased sensitivity to sound[7], Excitation[8], Respiratory depression[9], Respiratory arrest[10].

[1] Due to brainstem stimulation.
[2] During intramuscular injection.
[3] Due to disinhibition of the extra pyramidal system.
[4] When no concomitant muscle relaxant is administered.
[5] Tonic-clonic.
[6] The eyes remain open.
[7] During anaesthesia and in the recovery period.
[8] Motoric.
[9] Dose-related. Combination with respiratory depressant products may increase this respiratory effect.
[10] Particularly in cats.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

For intravenous use (i.v.): horses, cattle, dogs and cats.
For intramuscular use (i.m.): pigs, dogs and cats.
For subcutaneous use (s.c.): cats.

Ketamine can show large inter-individual variation in effect, and therefore dose rates administered should be tailored to the individual animal, dependent on factors such as age, condition, and the depth and duration of anaesthesia required. Prolongation of effect is possible by repeated administration of an optionally reduced initial dose.
For combination use: before ketamine is administered, please ensure that the animals are adequately sedated.

Horses
Pre-medication with a sedative is required for a sufficient anaesthetic effect:

To induce anaesthesia
With detomidine
Detomidine 20 µg/kg i.v., after 5 minutes
Ketamine 2.2 mg/kg fast i.v. (2.2 ml/100 kg)
Onset of action is gradual, taking approximately 1 minute to attain recumbency, with duration of anaesthetic effect lasting approximately 10 - 15 minutes.

With xylazine
Xylazine 1.1 mg/kg i.v., followed by
Ketamine 2.2 mg/kg i.v. (2.2 ml/100 kg)
Onset of action is gradual, taking approximately 1 minute, with duration of anaesthetic effect being variable and lasting 10 - 30 minutes but usually less than 20 minutes.

After injection the horse lays down spontaneously without any further help. If a distinct muscle relaxation is required simultaneously, muscle relaxants can be administered to the recumbent animal, until the horse shows first symptoms of relaxation.

Cattle
To avoid uncontrolled lying down and possible symptoms of excitation or for potentiation of anaesthesia a sedative premedication is recommended. To avoid hypoxia due to lateral or dorsal recumbency, oxygen can be administered through a nasal tube.

To induce anaesthesia
With xylazine
Xylazine 0.14 - 0.22 mg/kg i.v./i.m., followed by
Ketamine 2 - 5 mg/kg i.v. (2 - 5 ml/100 kg)
Onset of action is approximately 1 minute, with duration of anaesthetic effect lasting approximately 30 minutes.

The lower end of the stated dose range should be used when administering xylazine via the intravenous route.

Pigs
To induce anaesthesia
With azaperone
Ketamine 15 - 20 mg/kg i.m. (1.5 - 2 ml/10 kg) and 2 mg/kg azaperone IM.
In 4 – 5 month old pigs, following administration of 2 mg/kg azaperone and 20 mg/kg ketamine i.m.
the onset of anaesthesia took on average 29 minutes and duration of effect lasted about 27 minutes.

Dogs
Ketamine cannot be used as a mono-anaesthetic in dogs, as it causes an increased muscle tone and uncoordinated muscle contractions.

To induce anaesthesia

With medetomidine
Medetomidine 40 µg/kg i.m., followed by
Ketamine 5 - 7.5 mg/kg i.m. (0.5 - 0.75 ml/10 kg)
Duration of effect varies between 30 - 50 minutes and is dose related.

With xylazine
Xylazine 2 mg/kg i.m., after 10 minutes
Ketamine 10 mg/kg i.m. (1 ml/10 kg).
In dogs weighing more than 25 kg bodyweight reduce xylazine dosage to 1.3 mg/kg.
Onset of action is usually within 10 minutes and duration of effect lasts for approximately 30 minutes.

With diazepam
Administer diazepam 0.25 mg/kg i.v., immediately followed by
Ketamine 5 mg/kg i.v. (0.5 ml/10 kg).
Ketamine should be injected slowly and generally administered to effect, when used intravenously. Appropriate premedication should be used to ensure adequate sedation before administration of the diazepam-ketamine combination and to facilitate intubation. The optimal dosing regimen should be individually based on the pre-medication used. Average duration of effect is 10-20 minutes.

Cats
Mono-anaesthetic use of ketamine is possible, but to avoid undesired psychomotoric effects combined anaesthesia is recommended. Ketamine on its own may be used by intravenous injection, but intramuscular injection is the recommended route.
Ketamine should be injected slowly when administered intravenously.

As a sole agent
11 mg/kg ketamine i.m./i.v. for minor restraint,
22 - 33 mg/kg ketamine i.m./i.v.for minor surgery and restraint of fractious cats.
Duration of ketamine anaesthesia is 20 – 40 minutes and recovery takes place over a 1 – 4 hour period.

To induce anaesthesia (anaesthesia < 1 hour)
With medetomidine
Medetomidine 80 µg/kg i.m., followed by
Ketamine 5 – 7.5 mg/kg i.m. (0.25 - 0.4 ml/5 kg)

Onset of action is usually 3 - 4 minutes and duration of effect varies between 30 - 60 minutes and is dose related.

With xylazine
Xylazine 1 - 2 mg/kg i.m./s.c. and
Ketamine 10 - 20 mg/kg i.m./s.c. (0.5 - 1 ml/5 kg)
The lowest dose of xylazine (1 mg/kg) should be used, if ketamine is used at the highest dose (20 mg/kg).
Onset of action is usually within 5 minutes of ketamine administration and duration of effect lasts for at least 30 minutes.

Due to low dose volumes, the use of suitably calibrated measuring equipment, e.g. an insulin type syringe, is recommended.

The rubber stopper can be punctured safely a maximum of 25 times.

9. Advice on correct administration

See “Special warnings” in the package leaflet.

10. Withdrawal periods

Horses and cattle:
Meat and offal: zero days
Milk: zero hours

Pigs:
Meat and offal: zero days

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "Exp.". The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days
After first opening do not store above 25 °C.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes: 1 x 10 ml, 5 x 10 ml, 1 x 50 ml
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

<Local representatives <and contact details to report suspected adverse events>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

<17. Other information>