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

ketamine

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 100 mg ketamine (as hydrochloride)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
50 ml
5 x 10 ml

5. TARGET SPECIES

Horse, cattle, pig, dog, cat.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse, cattle, dog, cat: IV / pig, dog: IM / cat: IM, SC
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: zero days
Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

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

VetViva Richter GmbH, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57446/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {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 100 mg/ml injection

ketamine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ketamine (as hydrochloride) 100 mg/ml

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

10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Horse, cattle, dog, cat: IV / pig, dog: IM / cat: IM, SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Ketamidor 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

Marketing authorisation holder:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

Manufacturer responsible for batch release:
Richter Pharma AG, Durisolstrasse 14, 4600 Wels, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketamidor 100 mg/ml solution for injection

Ketamine

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

1 ml contains:

Active substance:
Ketamine (as hydrochloride) 100 mg

Excipient:
Benzethonium chloride 0.1 mg

Clear, colourless to almost colourless solution.

4. INDICATION(S)

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 product as a sole anaesthetic agent in any other species apart from the cat.

6. ADVERSE REACTIONS

Use of the intramuscular route of administration may be associated with pain.
Increased muscle tonus (due to disinhibition of the extra pyramidal system), rarely tachycardia and increase of blood pressure, salivation (due to brainstem stimulation). When no concomitant muscle relaxant is administered the increased muscle tonus may cause tremors or tonic-clonic convulsions. Concomitant effects of ketamine use may be motoric excitations, opened eyes, nystagmus (rhythmic eye movement), mydriasis (dilation of pupil) as well as increased sensibility especially against acoustic stimuli during anaesthesia and in the recovery period.
Ketamine causes a dose-related respiratory depression, which may lead to respiratory arrest particularly in cats. Combination with respiratory depressant products may increase this respiratory effect.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horse, cattle, pig, dog, cat.

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

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.
Administration is possible intravenously (horse, cattle, dog and cat), intramuscularly (pig, dog and cat) or in cats also subcutaneously.
For combination use: before ketamine is administered, please ensure that the animals are adequately sedated.

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

To induce anaesthesia
With detomidine:
Detomidine 20 µg/kg IV, after 5 minutes
Ketamine 2.2 mg/kg fast IV (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 IV, followed by
Ketamine 2.2 mg/kg IV (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 IV/IM, followed by
Ketamine 2 - 5 mg/kg IV (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.

PIG
To induce anaesthesia
With azaperone
Ketamine 15 - 20 mg/kg IM (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 IM the onset of anaesthesia took on average 29 minutes and duration of effect lasted about 27 minutes.

DOG
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 IM, followed by
Ketamine 5 - 7.5 mg/kg IM (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 IM, after 10 minutes
Ketamine 10 mg/kg IM (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 IV, immediately followed by
Ketamine 5 mg/kg IV (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.

CAT
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 IM/IV for minor restraint,
22 - 33 mg/kg ketamine IM/IV 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 IM, followed by
Ketamine 5 – 7.5 mg/kg IM (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 IM/SC and
Ketamine 10 - 20 mg/kg IM/SC (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, it is recommended to use an insulin type syringe to accurately measure dosages.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

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

Pig:
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 WARNING(S)

Special precautions for use in animals:
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.

Pregnancy and lactation:
Ketamine crosses the placental barrier. Ketamine should not be used in the periparturient period.
The use of the 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 (symptoms, emergency procedures, 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.

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

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 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.

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 product should be disposed of in accordance with local requirements.

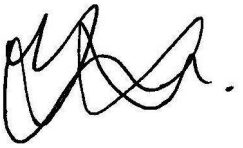
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

15. OTHER INFORMATION

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

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



Approved: 23 January 2023