A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE PACKAGE

Boxes with 1 and 10 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketabel 100 mg/ml solution for injection for dogs, cats, cattle, sheep, goats, horses, pigs and laboratory animals.
Ketamine

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains
ketamine 100 mg
(equivalent to ketamine hydrochloride 115.34 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
25 ml
10 x 10 ml
10 x 25 ml

5. TARGET SPECIES

Dogs, cats, cattle, sheep, goats, horses, pigs, guinea pigs, hamsters, rabbits, rats and mice

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat, offal: 1 day
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

bela-pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41816/4003

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 10 and 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketabel 100 mg/ml Solution for injection
Ketamine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

100 mg/ml Ketamine

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

10 ml
25 ml

4. ROUTE(S) OF ADMINISTRATION

IV, IM, IP

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat, offal: 1 day
Milk: zero hours.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Ketabel 100 ml/ mg solution for Injection for dogs, cats, cattle, sheep, goats, horses, pigs and laboratory animals

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

Marketing authorisation holder and manufacturer responsible for batch release:
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketabel 100 mg/ml solution for Injection for dogs, cats, cattle, sheep, goats, horses, pigs and laboratory animals

Ketamine

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

Each ml contains:

Active substance:

Ketamine	100 mg
(equivalent to ketamine hydrochloride	115.34 mg)

Excipients:

Chlorobutanol hemihydrate	5 mg

Clear, colourless solution for injection

4. INDICATION(S)

The product may be used in combination with a sedative for:
- Immobilisation
- Sedation
- General anaesthesia

5. CONTRAINDICATIONS

Do not use in animals presenting with:
- severe hypertension,
- cardio-respiratory deficiency,
- hepatic or renal dysfunction.

Do not use in animals with glaucoma.
Do not use in animals with eclampsia or pre-eclampsia.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.
Do not use the product as a sole anaesthetic agent in any of the target species.

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 ocular surgical interventions;
Do not use in animals undergoing a myelogram procedure

6. ADVERSE REACTIONS

In anaesthetised animals, mainly during and after the awakening phase, cardio-respiratory disorders (cardiac arrest, hypotension, dyspnoea, bradypnoea, pulmonary oedema) associated or not with neurological disorders (convulsions, prostration, trembling) and systemic disorders (hypersalivation, pupillary anomaly) have been observed in rare cases.
Salivation has been very rarely reported in cats.
An increase in skeletal muscle tone has been very rarely reported in cats, dogs, horses, rabbits, cattle and goats.
Dose-dependent respiratory depression, which may lead to respiratory arrest, has been very rarely reported in cats, dogs, rabbits, cattle and goats. The combination of respiratory depressant products may amplify this effect.
An increase in heart rate has been very rarely reported in cats and dogs. An increase in blood pressure with an increased tendency to bleed has been very rarely reported in dogs.
Muscular twitching and tonic convulsions have been reported in the cat at the recommended dose rates.
In cats, in very rare cases, the eyes remain open, with mydriasis and nystagmus.
Reactions during awakening - ataxia, hypersensitivity to stimuli, excitement - have been rarely and very rarely reported in horses and dogs, respectively.
Pain on intramuscular injection has been very rarely reported in cats.

All adverse reactions and frequencies are from spontaneous reports (pharmacovigilance).

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.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Dogs, cats, cattle, sheep, goats, horses, pigs, guinea pigs, hamsters, rabbits, rats, and mice

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

For slow intravenous and intramuscular administration.In laboratory animals, the intraperitoneal route can also be used. Ketamine should be combined with a sedative.
One dose of 10 mg of ketamine per kg bodyweight corresponds to 0.1 ml of a 100 mg/ml solution per kg bodyweight.
For intramuscular injection maximum volume per injection site is 20 ml.
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.
Before ketamine is administered, please ensure that the animals are adequately sedated.
The following dosing advices show possible combinations with ketamine, the concomitant use of other pre-anaesthetics, anaesthetics or sedatives should be subject to a benefit/risk assessment by the responsible veterinarian.

Dog

Combination with xylazine or medetomidine
Xylazine (1.1 mg/kg IM) or medetomidine (10 to 30 µg/kg IM) can be used with Ketamine (5 to 10 mg/kg i.e. 0.5 to 1 ml/10 kg IM) for short term anesthesia of 25 to 40 min. The ketamine dose can be adjusted, depending on the desired duration of surgery.
In case of intravenous use, the dose must be reduced to 30 - 50 % of the recommended intramuscular dose.

Cat

Combination with xylazine

Xylazine (0.5 to 1.1 mg/kg IM) with or without atropine is administered 20 min before ketamine (11 to 22 mg/kg IM i.e. 0.11 to 0.22 ml/kg IM).

Combination with medetomidine

Medetomidine (10 to 80 µg/kg IM) can be combined with ketamine (2.5 to 7.5 mg/kg IM i.e 0.025 to 0.075ml/kg IM). The dose of ketamine should be reduced as the dose of medetomidine increases.

Horse

Combination with detomidine:

Detomidine 20 µg/kg IV, after 5 minutes ketamine 2.2 mg/kg fast IV (2.2 ml/100 kg IV)
Onset of action is gradual, taking approximately 1 minute to attain recumbency, with duration of anaesthetic effect lasting approximately 10 - 15 minutes.

Combination with xylazine:

Xylazine 1.1 mg/kg IV, followed by ketamine 2.2 mg/kg IV (2.2 ml/100 kg IV)
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

Combination with xylazine:

Intravenous use:
Adult cattle can be anesthetized for short periods with xylazine (0.1 mg/kg IV) followed by ketamine (2 mg/kg IV i.e. 2 ml/100kg IV). Anesthesia lasts approximately 30 min but can be pro-longed for 15 min with additional ketamine (0.75 to 1.25 mg/kg IV i.e. 0.75 to 1.25 ml/100kg IV).

Intramuscular use:

Ketamin and Xylazine doses should be doubled in case of intramuscular administration.

Sheep, goat

Intravenous use:

Ketamine 0.5 to 22 mg/kg IV i.e. 0.05 to 2.2 ml/10 kg IV depending on the sedative used.

Intramuscular use:

Ketamine 10 to 22 mg/kg IM i.e. 1.0 to 2.2 ml/10kg IM depending on the sedative used.

Pig

Combination 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.

Laboratory animals

Combination with xylazine
Rabbits: xylazine (5-10 mg/kg IM) + ketamine (35-50 mg/kg IM i.e. 0.35 to 0.50 ml/kg IM)
Rats: xylazine (5-10 mg/kg IP, IM) + ketamine (40-80 mg/kg IP, IM i.e. 0.4-0.8 ml/kg IP, IM)
Mice: xylazine (7.5-16 mg/kg IP) + ketamine (90-100 mg/kg IP i.e. 0.9 to 1.0 ml/kg IP)

Guinea pigs: xylazine (0.1 to 5 mg/kg IM) + ketamine (30-80 mg/kg IM i.e. 0.3 to 0.8 ml/kg IM)
Hamster: xylazine (5 to 10 mg/kg IP) + ketamine (50 to 200 mg/kg IP i.e. 0.5 to 2 ml/kg IP)

Dose for maintenance of anaesthesia:
When needed, prolongation of effect is possible by repeated administration of an optionally reduced initial dose.
The vial can be broached up to 50 times. The user should choose the most appropriate vial size according to the target species to be treated and the administration route.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable

10. WITHDRAWAL PERIOD(S)

Cattle, sheep, goats and horses:
Meat and offal: 1 day.
Milk: zero hours.

Pigs:
Meat and offal: 1 day.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

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 inhalational anaesthetics is indicated.
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 α2-receptor-agonists, anaesthetics, neuroleptanalgesics, tranquillisers and inhalational anaesthetic agents.
UK: When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product

remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Special precautions for use in animals:

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.
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.
When used in combination with other products, consult the contraindications and warnings that appear on the relevant data sheets.
The eyelid reflex stays intact.
Twitching, as well as excitation upon recovery, may be possible. It is important that both premedication and recovery should occur in quiet and calm surroundings. To ensure a smooth recovery appropriate analgesia and premedication should be administered, if indicated.
The concomitant use of other pre-anaesthetics or anaesthetics should be subject to a benefit/risk assessment, taking into account the composition of the used medicines and their doses and the nature of the intervention. The recommended doses of ketamine are likely to vary depending on the concomitant pre-anaesthetics and anaesthetics used.
The prior administration of an anticholinergic such as atropine or glycopyrrolate to prevent the occurrence of adverse effects, especially hypersalivation, may be considered after a benefit/risk assessment by the veterinarian.
Ketamine should be used with caution when pulmonary disease is present or suspected.
Animals should be fasted for a period prior to anaesthesia where possible.
In small rodents cooling down should be prevented.

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-injection.
People with known hypersensitivity to ketamine or propylene glycol 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.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE.
Do not use the product if you know you are sensitive to propylene glycol.

Advice to doctors:

Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

Pregnancy and lactation:

Ketamine passes the blood placenta barrier very well to enter the fetal blood circulation in which 75 to 100 % of the maternal blood levels can be reached. This partially anaesthetises neonates delivered by caesarean section. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Neuroleptics, tranquillisers and chloramphenicol increase the anaesthetic effect of ketamine.
Barbiturates, opiates and diazepam may prolong time to recovery.
Effects may be cumulative. A decrease of the dose of one or both agents may be necessary.

There is a possibility of an increased risk of cardiac arrhythmia when ketamine is used in combination with thiopental or halothane. Halothane prolongs the half-life of ketamine.
Simultaneous intravenous administration of a spasmolytic agent may provoke a collapse.
Theophylline, when given with ketamine, may provoke an increase of epileptic crises.
When detomidine is used together with ketamine, the recovery is slower than when ketamine is used alone.
Refer also note section “Special warnings for each target species”.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose CNS effects (e.g. seizures), apnoea, cardiac arrhythmia, dysphagia and respiratory depression or 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:
Due to a chemical incompatibility, do not mix barbiturates or diazepam with ketamine in the same syringe.

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

June 2021

15. OTHER INFORMATION

Carton with 1 x 10 ml
Carton with 10 x 10 ml
Carton with 1 x 25 ml
Carton with 10 x 25 ml

Not all pack sizes may be marketed.

Approved: 13 May 2024