1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketabel 100 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ketamine	100 mg
(equivalent to ketamine hydrochloride	115.34 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorobutanol hemihydrate	5mg
Propylene glycol	
Water for injections	

Clear, colourless solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 or if symptoms develop after ocular/oral contact, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE, as sedation may occur.
Advice to doctors: 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

Sheep, pigs, guinea pigs, hamsters, rats and mice:

Rare (1 to 10 animals / 10,000 animals treated):	Cardiac arrest[1], Hypotension[1] Dyspnoea[1], Bradypnoea[1], Pulmonary oedema[1] Convulsion[1], Trembling[1] Prostration[1] Hypersalivation[1] Pupil disorder[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Mydriasis[2] Nystagmus[2]

[1]mainly during and after the awakening phase
[2]while eyes remain open

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Cardiac arrest[1], Hypotension[1] Dyspnoea[1], Bradypnoea[1], Pulmonary oedema[1] Convulsion[1], Trembling[1] Prostration[1] Hypersalivation[1] Pupil disorder[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Mydriasis[2] Nystagmus[2], Muscular hypertonicity Respiratory depression[3] Tachycardia Immediate pain upon injection[4]
Undetermined frequency (cannot be estimated based on available data):	Twitching, Tonic seizures

[1]mainly during and after the awakening phase
[2]while eyes remain open
[3]dose-dependent, may lead to respiratory arrest; a combination with respiratory depressant products may amplify this effect
[4]after intramuscular injection

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Cardiac arrest[1], Hypotension[1] Dyspnoea[1], Bradypnoea[1], Pulmonary oedema[1] Convulsion[1], Trembling[1] Prostration[1] Hypersalivation[1]

	Pupil disorder[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Mydriasis[2] Nystagmus[2], Ataxia[6], Hyperaesthesia[6], Muscular hypertonicity Respiratory depression[3] Tachycardia, Hypertension Haemorrhage[5] Agitation[6]

[1]mainly during and after the awakening phase
[2]while eyes remain open
[3]dose-dependent, may lead to respiratory arrest; a combination with respiratory depressant products may amplify this effect
[5]the increased tendency to bleed occurs as a result of the hypertension
[6]during awakening

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Cardiac arrest[1], Hypotension[1] Dyspnoea[1], Bradypnoea[1], Pulmonary oedema[1] Convulsion[1], Trembling[1], Ataxia[6], Hyperaesthesia[6] Prostration[1] Hypersalivation[1] Pupil disorder[1] Agitation[6]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Mydriasis[2] Nystagmus[2], Muscular hypertonicity

[1]mainly during and after the awakening phase
[2]while eyes remain open
[6]during awakening

Cattle, goats and rabbits:

Rare (1 to 10 animals / 10,000 animals treated):	Cardiac arrest[1], Hypotension[1] Dyspnoea[1], Bradypnoea[1], Pulmonary oedema[1] Convulsion[1], Trembling[1] Prostration[1] Hypersalivation[1] Pupil disorder[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Mydriasis[2] Nystagmus[2], Muscular hypertonicity Respiratory depression[3]

[1]mainly during and after the awakening phase
[2]while eyes remain open
[3]dose-dependent, may lead to respiratory arrest; a combination with respiratory depressant products may amplify this effect

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 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.

Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 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 3.4 “Special warnings”.

3.9 Administration routes and dosage

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 provide 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QN01AX03

4.2 Pharmacodynamics

Ketamine blocks nerve impulses in the cerebral cortex while activating subjacent brain regions. Hence, a dissociative anaesthesia is obtained, on the one hand narcosis and superficial analgesia and, on the other hand no bulbar depression, continued muscle tone and maintenance of certain reflexes (e.g. swallowing reflex).
At anaesthetic doses, ketamine is a bronchodilator (sympathomimetic effect), increases heart rate and blood pressure, and increases cerebral circulation and intraocular pressure.
These characteristics can be modified if the veterinary medicinal product is used in association with other anaesthetics.

4.3 Pharmacokinetics

Ketamine is rapidly distributed in the organism. The plasma protein binding of ketamine is 50%. Ketamine shows affinity to certain tissues, and increased concentrations have been found in the liver and kidneys. The majority of ketamine is excreted via kidney. Ketamine is extensively metabolised, however species specific characteristics can be observed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

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

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

10 ml, 25 ml brown glass vials type I with red brombutyl stopper and aluminium capsule

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Bela-Pharm GmbH & Co. KG

7. MARKETING AUTHORISATION NUMBER(S)

VPA10445/005/001

8. DATE OF FIRST AUTHORISATION

03/07/2020

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

06/10/2025

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).