Ketabel 100 mg/ml

Solution for Injection

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

Ketamine

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 Strase 19
49377 Vechta / Germany

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

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

INDICATION(S)

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

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

ADVERSE REACTIONS

Ketamine may cause excessive salivation in cats.
Ketamine causes an increased tonus of skeletal muscles. 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.
Ketamine increases the heart rate and increases arterial blood pressure with concurrent increased bleeding tendency.
Muscular twitching and tonic convulsions have been reported in the cat at the recommended dose rates.
In cats and dogs eyes remain opened with mydriasis and nystagmus.
Emergence reactions - ataxia, hypersensitivity to stimuli, excitation – may occur during recovery.
There may be some pain on intramuscular injection.

TARGET SPECIES

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

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.

ADVICE ON CORRECT ADMINISTRATION
Not applicable

WITHDRAWAL PERIOD(S)

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

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.

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.

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.

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.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
20.05.2020

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.

Marketing authorisation number: 6501046.00.00 (Germany)
For animal treatment only.
Available on prescription only!

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