anaestamine® 100mg/ml

Solution for Injection
Ketamine

Statement of the active substances and other ingredients
Description:
Clear, colourless aqueous solution.
Composition per ml:
Active substance:
Ketamine 100mg
(equivalent to 115.33mg ketamine hydrochloride).
Excipients:
Chlorocresol 1mg

Indications
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 species.
Do not use in ocular surgical interventions.

Adverse reactions
Ketamine may cause 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.
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.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

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

Dosage for each species, route(s) and method of administration
For intravenous and intramuscular administration. In laboratory animals, intraperitoneal route can be used too.
One dose of 10mg of ketamine per kg bodyweight corresponds to 0.1ml of a 100mg/ml solution per kg bodyweight.
Before ketamine is administered, please ensure that the animals are adequately sedated.

DOG
Combination with xylazine or medetomidine:
Xylazine (1.1mg/kg IM) or medetomidine (10 to 30µg/kg IM) can be used with Ketamine (5 to 10mg/kg i.e. 0.5 to 1ml/10kg IM) for short term anaesthesia of 25 to 40 min. The ketamine dose can be adjusted, depending on the desired duration of surgery.

CAT
Combination with xylazine:
Xylazine (0.5 to 1.1mg/kg IM) with or without atropine is administered 20 min before ketamine (11 to 22mg/kg IM i.e. 0.11 to 0.22ml/kg IM).
Combination with medetomidine:
Medetomidine (10 to 80µg/kg IM) can be combined with ketamine (2.5 to 7.5mg/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 20µg/kg IV, after 5 minutes ketamine 2.2mg/kg fast IV (2.2ml/100kg 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 1.1mg/kg IV, followed by ketamine 2.2mg/kg IV (2.2ml/100kg 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:
Adult cattle can be anaesthetised for short periods with xylazine (0.1 to 0.2mg/kg IV) followed by ketamine (2mg/kg IV i.e. 2ml/100kg IV). The lower dose of xylazine is used when cattle weigh more than 600kg. Anaesthesia lasts approximately 30 min but can be prolonged for 15 min with additional ketamine (0.75 to 1.25mg/kg IV i.e. 0.75 to 1.25ml/100kg IV).

SHEEP
Ketamine 7.5 to 22mg/kg IV i.e. 0.75 to 2.2ml/10kg IV depending on the sedative used.

GOAT
Ketamine 11 to 22mg/kg IM i.e. 1.1 to 2.2ml/10kg IM depending on the sedative used.

PIG
Combination with azaperone:
Ketamine 15 - 20mg/kg IM (1.5 - 2ml/10kg) and 2mg/kg azaperone IM.
In 4–5 month old pigs, following administration of 2mg/kg azaperone and 20mg/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 (5-10mg/kg IM) + ketamine (35-50mg/kg IM i.e. 0.35 to 0.50ml/kg IM).
Rats: xylazine (5-10mg/kg IP, IM) + ketamine (40-80mg/kg IP, IM i.e. 0.4-0.8ml/kg IP, IM).
Mice: xylazine (7.5-16mg/kg IP) + ketamine (90-100mg/kg IP i.e. 0.9 to 1.0ml/kg IP).
Guinea pigs: xylazine (0.1 to 5mg/kg IM) + ketamine (30-80mg/kg IM i.e. 0.3 to 0.8ml/kg IM).
Hamster: xylazine (5 to 10mg/kg IP) + ketamine (50 to 200mg/kg IP i.e. 0.5 to 2ml/kg IP).
Dose for maintenance of anaesthesia:
When needed prolongation of effect is possible by repeated administration of an optionally reduced initial dose.

Advice on correct 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.
The vial can be broached up to 20 times. The user should choose the most appropriate vial size according to the target species to be treated and the administration route.

Withdrawal period
Cattle, sheep, goats and horses:
Meat and offal: 1 day. Milk: zero days.
Pigs: Meat and offal: 1 day.

Special storage precautions
Keep out of the sight and reach of children.
Store the vial in the original packaging in order to protect from light. Store the vial upright. Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days.

Special warnings
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 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 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.
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-administration.
People with known hypersensitivity to ketamine or any of the excipients 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 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 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 accordingly to the benefit/risk assessment by the responsible veterinarian.
Interaction with other medicinal products and other forms of interaction:
Neuroleptics, tranquillisers, cimetidine and chloramphenicol potentiate ketamine anaesthesia.
Barbiturates, opiates and diazepam may prolong the recovery time.
Effects may be potentiated. 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.
The 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.
Overdose (symptoms, emergency procedures, antidotes):
In case 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:
Due to a chemical incompatibility, do not mix barbiturates or diazepam with ketamine in the same syringe.
The product must not be mixed with other veterinary medicinal products, with the exception of the infusion fluids 0.9% sodium chloride, Ringers solution and lactated Ringers solution.

Special precautions for the disposal of unused product or waste material, if any
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: September 2014

Other information
10ml, 30ml and 50ml clear type I glass vials closed with a bromobutyl rubber stopper and aluminium cap in a carton box containing 10ml, 25ml and 50ml product, respectively.
Not all pack sizes may be marketed.

For animal treatment only.

Marketing Authorisation Holder:
Le Vet Beheer B.V., Wilgenweg 7,
3421 TV Oudewater, The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V., Forellenweg 16
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