SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol-Lipuro Vet 10 mg/ml emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml emulsion contains:

Active substance:
Propofol 10 mg

Excipients:

Qualitative composition of excipients and other constituent
Soya-bean oil
Medium-chain triglycerides
Glycerol
Egg lecithin
Sodium oleate
Water for injections

Emulsion for injection.
White milky oil-in-water emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

A short–acting, intravenous, general anaesthetic for procedures of short duration, lasting up to five minutes.

For induction and short-term maintenance of general anaesthesia using incremental doses to effect.

For induction of general anaesthesia where maintenance is provided by inhalation anaesthetics.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The product is a stable emulsion; discard the container if phase separation is observed.

If injected slowly, an inadequate plane of anaesthesia can occur.

3.5 Special precautions for use

Special precautions for safe use in the target species:

During induction of anaesthesia, mild hypotension and transient apnoea, similar to effects with other intravenous anaesthetic agents, may occur. Facilities for the maintenance of a patent airway, artificial ventilation and oxygen enrichment should be available.
Following induction of anaesthesia, the use of an endotracheal tube is recommended. Increased levels of carbon dioxide in blood have been reported with increased duration of propofol anaesthesia. It is advisable to administer supplemental oxygen during maintenance of anaesthesia. In addition the need for assisted ventilation should be considered during prolonged anaesthesia.

If the veterinary medicinal product is injected too rapidly, cardiopulmonary depression may occur (apnoea, bradycardia, hypotension).
As with other intravenous anaesthetic agents, caution should be exercised in dogs and cats with cardiac, respiratory, renal or hepatic impairment, or in hypovolaemic or debilitated animals.

Propofol may increase blood glucose metabolism and insulin secretion in healthy dogs. In the absence of safety data in diabetic animals, use only after a benefit/risk assessment by the veterinarian.

Care should be taken when administering the veterinary medicinal product to patients with hypoproteinaemia, hyperlipidaemia or very thin animals since these animals may be more susceptible to adverse effects.

The safety of the veterinary medicinal product has not been established in dogs or cats younger than 4 months and should be used in these animals only according to the risk/benefit assessment by the responsible veterinarian.

It has been reported that the clearance of propofol is slower in overweight/obese animals and dogs over 8 years of age. Extra care should be taken when administering the veterinary medicinal product to these animals; in particular, a lower dose of propofol may be adequate for induction and maintenance in such cases. Sighthounds have been reported to show a slower clearance of propofol and may have a slightly longer duration of recovery from anaesthesia compared to other breeds of dog.

Propofol does not have analgesic properties, therefore supplementary analgesic agents should be provided in cases where procedures are anticipated to be painful. When propofol is used concomitantly with opioids, an anticholinergic agent (e.g. atropine) may be used in cases of bradycardia according to the benefit/risk assessment by the responsible veterinarian. See section 3.8.

Use aseptic techniques when administering the product as it does not contain an antimicrobial preservative.

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. Preferably use a guarded needle until the moment of injection. Ampoules, particularly, should be opened with care to avoid cutting oneself.

Wash off splashes from the skin and eyes immediately.

In the case of accidental self-administration, seek medical advice immediately and show the package leaflet or label to the physician, but DO NOT DRIVE as sedation may occur.

Advice to doctor: 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

Dogs

Very common (>1 animal / 10 animals treated)	Apnoea
Common (1 to 10 animals / 100 animals treated):	Excitation Arrhythmia, Bradycardia, Hypotension, Hypertension[a] Emesis, Hypersalivation, Retching Paddling, Myoclonus, Nystagmus, Opisthotonus, Recovery prolonged[b] Sneezing Face/nose rubbing
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site pain[c] Hyperglycemia

[a] If propofol is used without premedication as a sole agent in induction of anaesthesia, a short transient increase of arterial blood pressure can be observed.
[b] Slow recovery
[c] After intravenous administration

Cats

Very common (>1 animal / 10 animals treated)	Apnoea
Common (1 to 10 animals / 100 animals treated):	Excitation Arrhythmia, Bradycardia, Hypotension Emesis, Hypersalivation, Retching Paddling, Myoclonus, Nystagmus, Opisthotonos, Recovery prolonged Sneezing Face/nose rubbing
Uncommon (1 to 10 animals / 1 000	Injection site pain[a]

animals treated):	Diarrhoea[b] Facial oedema[b,c] Hyperglycemia, Heinz body anaemia[b] Anorexia[b]

[a] After intravenous administration.
[b] In cats undergoing repeated anaesthesia. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood. The effects are generally transient and resolve on their own.
[c] Mild facial oedema.

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

Pregnancy and lactation
The safety of propofol in foetuses/neonates and during lactation has not been established.
Propofol has not been used in dogs and cats where the pregnancy is to be maintained, but been used successfully for induction prior to 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

Propofol has been used in association with commonly used premedicants, e.g. atropine, glycopyrrolate, α-2 agonists (medetomidine, dexmedetomidine), acepromazine, benzodiazepines (diazepam, midazolam); inhalational agents (halothane, isoflurane, sevoflurane, nitrous oxide, enflurane); and analgesic agents such as pethidine and buprenorphine.

The veterinary medicinal product may be administered parallel to all intravenous fluids via e.g. a Y-piece positioned near the injection site.

No pharmacological incompatibility has been encountered.
The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration.

The concurrent use of sedative or analgesic drugs is likely to reduce the dose of propofol required to induce and maintain anaesthesia.

Concomitant use of propofol and opioids may cause significant respiratory depression and a profound decrease in heart rate. In cats, concurrent use of propofol and ketamine have been reported to cause apnoea more frequently than propofol and other premedicants. To reduce the risk of apnoea, propofol should be administered slowly over 20–60 seconds.

Co-administration of propofol and opioid (e.g. fentanyl, alfentanil) infusions for

maintenance of general anaesthesia may result in a prolonged recovery. Cardiac arrest has been observed in dogs that received propofol followed by alfentanil.

Administration of propofol with other medicinal products that are metabolised by cytochrome P450 (isoenzyme 2B11 in the dog) such as chloramphenicol, ketoconazole and loperamide reduces propofol clearance and prolongs recovery from anaesthesia.

3.9 Administration routes and dosage

Administration: By intravenous injection.
Before opening the container, the product should be inspected visually for the absence of visible droplets or extraneous foreign particles and discarded if present. The container should be shaken gently but thoroughly before opening.

Induction: The induction dose is computed according to bodyweight and may be administered to effect over a period of 10 – 40 seconds. Alternatively, the computed dose may be given in full as a single bolus. The induction dose is reduced by the use of premedicants.

It should be noted that the dose rates shown are for guidance and in practice the dose rate should be based on response.

The average induction dose for dogs and cats, either unpremedicated or when premedicated with a non alpha-2-agonist tranquilliser such as acepromazine, is as follows:

	Dose rate mg/ kg bodyweight	**Dose volume ml/ kg bodyweight**
Dogs		
Unpremedicated	6.5	6.5 ml/ 10kg
Premedicated	4.0	4.0 ml/ 10 kg
Cats		
Unpremedicated	8.0	2.0 ml/ 2.5 kg
Premedicated	6.0	1.5 ml/ 2.5 kg

Maintenance by Propofol-Lipuro Vet 10 mg/ml: Where anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Incremental doses should be given to effect. Experience in clinical trials has shown that doses of around 1ml per 4.0 – 8.0 kg bodyweight sustain anaesthesia for periods of up to five minutes.

Maintenance by inhalation agents: Where inhalation agents are used to maintain general anaesthesia, clinical experience indicates that there may be a need to use a higher initial concentration of inhalation agent than is normally the case following induction with barbiturate agents such as thiopentone.

The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration.

Propofol-Lipuro Vet 10 mg/ml does not contain an antimicrobial preservative. It should be used immediately after opening. Any product remaining in the container following withdrawal of the required dose should be discarded.

Continuous and prolonged exposure may lead to slower recovery, particularly in cats.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Accidental overdosage is likely to cause cardio-respiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression requires the use of plasma expanders and pressor agents.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

Propofol-Lipuro Vet 10 mg/ml emulsion for injection belongs to pharmacotherapeutic group: general anaesthetics, propofol

4.1 ATCvet Code: QN01AX10.

4.2 Pharmacodynamics

Propofol is a substituted phenol which, when given by intravenous injection, is a short-acting anaesthetic with a rapid rate of onset. Recovery from anaesthesia is usually rapid.

4.3 Pharmacokinetics

After a single bolus administration, blood level profiles are characterised by a rapid distribution phase and a rapid elimination phase. No accumulation of propofol in blood has been observed after multiple daily dosing.

Propofol is metabolised by the liver. Urinary excretion is the major route of elimination of metabolites from the body.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 Years

5.3 Special precautions for storage

Do not store below 25 ºC. Do not freeze.

Any product remaining in the container following withdrawal of the required dose should be discarded.

5.4 Nature and composition of immediate packaging

Ampoules:
20 ml one-cut clear, colourless type I glass ampoule. Ampoules are packed into boxes each containing 5 ampoules.

Glass vials:
20 ml colourless type II glass vials, sealed with rubber stoppers. Vials are packed into boxes each containing 10 vials

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

B. Braun Melsungen AG

7. MARKETING AUTHORISATION NUMBER

Vm 03551/4001

8. DATE OF FIRST AUTHORISATION

14 June 2002

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

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall

Approved 22 February 2026