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

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

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

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

4.5 Special precautions for use

(i) Special precautions for use in animals

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.

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.

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

(ii) 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 event of accidental self-administration, seek urgent medical attention and show the label.

Advice to doctor: Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

4.6 Adverse reactions (frequency and seriousness)

Side-effects during induction, maintenance and recovery are uncommon. Induction is generally smooth, with minimal evidence of excitation. During the recovery phase, vomiting and evidence of excitation have been observed in a small proportion of animals.

In clinical trials in cats and dogs, transient apnoea during induction has been observed frequently. In cats, sneezing, occasional retching and a paw/ face licking characteristic during recovery have been observed in a small proportion of cases.

If panting is evident before induction, it may continue throughout the subsequent periods of anaesthesia and recovery.

Inadvertent perivascular administration rarely causes local tissue reactions.

Repeated anaesthesia with propofol in cats may cause oxidative injury and Heinz body formation. Recovery may also become prolonged. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood.

4.7 Use during pregnancy, lactation or lay

The safety of propofol in fetuses/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.

4.8 Interaction with other medicinal products and other forms of interaction

Propofol has been used in association with commonly used premedicants, e.g. atropine, acepromazine, diazepam; inhalational agents, e.g. halothane, nitrous oxide, enflurane; and analgesic agents, e.g. pethidine, buprenorphine.
No pharmacological incompatibility has been encountered.

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

4.9 Amount(s) to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Propofol-Lipuro Vet 10 mg/ml emulsion for injection belongs to pharmacotherapeutic group: general anaesthetics, propofol
ATCvet Code: QN01AX10.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya-bean oil,
Medium-chain triglycerides,
Glycerol,
Egg lecithin,
Sodium oleate,
Water for injections,

6.2 Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products or infusion fluids prior to administration.

6.3 Shelf life

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

6.4 Special precautions for storage

Store below 25 ºC. DO NOT FREEZE.

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Germany

Postal address:
B. Braun Melsungen AG
34209 Melsungen

8 MARKETING AUTHORISATION NUMBER

Vm 03551/4001

9. DATE OF FIRST AUTHORISATION

14 June 2002

10. DATE OF REVISION OF THE TEXT

September 2017

Approved: 19 September 2017